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340B Program

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		President's Budget	+/- FY 2023 Enacted
340B Drug Pricing Program/Office of Pharmacy Affairs	12,238	17,238	+5,000

TALKING POINTS:

- The 340B Program is a critical drug discount program for safety net providers that serves **every congressional district** in the country.
 - Eligible entities include community health centers, Ryan White HIV/AIDS clinics, rural hospitals, and children's hospitals.
- I know that **program integrity** is critical and that is why the President's budget includes proposals to strengthen compliance, transparency and integrity of the program.
 - Right now, HHS does not have the authority to require reporting by covered entities on how they spend their savings. This budget requests new regulatory authority to require covered entities to annually report to HHS how the savings achieved through the Program benefits the communities they serve.
 - The Budget also proposes explicit regulatory authority to strengthen compliance and transparency related to the use of contract pharmacies.
- The Biden-Harris Administration is committed to **lowering the cost of drugs** and increasing access to affordable care. The 340B program is critical to this work and I look forward to working with Congress on these proposals to strengthen the program.

Questions:

Q: What is in the FY 2024 Budget for the 340B program? Why are you asking for more funding if the hospitals are exploiting the program?

- The FY 2024 Budget Request for the 340B Program is \$17.2 million, an increase of \$5 million over FY 2023, to strengthen the program's operations.
- The FY 2024 Budget includes a proposal to enhance 340B Program integrity by requiring covered entities to annually report to HHS on how the savings achieved through the Program benefits the communities they serve and provide HHS regulatory authority to implement this requirement.
- The Budget also proposes explicit regulatory authority to strengthen compliance and transparency related to the use of contract pharmacies.
- We look forward to working with Congress on these proposals to strengthen the 340B Program.

988 Implementation

TALKING POINTS:

- 988 is more than a number, it's a message: we're there for you. The transition to 988 is just the beginning. We are working towards comprehensive, responsive crisis care services nationwide to save lives.
- Investments in the 988 Lifeline through FY23 appropriations and the Bipartisan Safer Communities Act expanded lifesaving behavioral health services across the country.
- The FY24 budget requests an increase of over \$334 million to scale and strengthen the 988 crisis care enterprise for the 9 million contacts anticipated in FY2024.

QUESTIONS:

Q: How many contacts did the Lifeline answer last year? How quickly?

- From July 2022 to January 2023, the 988 Lifeline answered 2,248,545 million contacts.
- Thanks to historic investments made by Congress, calls answered increased by 57%, chats answered increased by 264%, and texts answered increased by 1608% between January 2022 and January 2023.
- The average speed to answer across all contacts decreased from 181 seconds to 40 seconds.

Q: Does the 988 Lifeline take calls in Spanish?

- Yes, in 2022, the 988 Lifeline increased the number of call centers taking Spanish calls -- this includes, most recently, Beacon in New Hampshire and Linea Pas in Puerto Rico, which were both added in November.
- SAMHSA is working to add Spanish chat and text services by October of this year and is focused on supporting the Spanish crisis center workforce with trainings and webinars in Spanish.

Q: I heard that there was a Lifeline outage in December 2022 as a result of a malicious attack. What steps is SAMHSA taking to ensure that the Lifeline is secure?

- Our highest priorities are to develop additional redundancies in the event of any future outages, minimize the likelihood of these events, continue to protect personal information, and to be sure there are clear communications protocols among partners and the public to quickly resolve problems if they arise.

Q: What is the response rate right now for text, chat and calls?

- The total overall contacts has been above 400k each month and continues to trend up. Accordingly, we are projecting roughly 6 million contacts for FY2023 and the need to support 9 million contacts in FY2024.
- Since July 2022, we have maintained above a 95% response rate for chat and text.

- There was increase in the call response rate from Aug (i.e., 84%) to Jan (i.e., 88%). This is also notable as the contacts increase and we work to expand access and strengthen the network.

Q: Was any personal information obtained, as a result of this attack?

- Based on all available evidence that we have reviewed at this point, it is unlikely that any data were breached or exfiltrate

Abortion Riders

TALKING POINTS:

- I understand people have deeply held beliefs on this issue and I respect that.
- Reproductive health decisions should be between a patient and doctor.
- HHS will continue to enforce the law.

Questions:

Q: The budget excludes the Hyde amendment. Are you going to ignore the law?

- As you know, this is a provision included in funding bills passed by Congress, so it will be up to Congress on whether that changes.

Q: Do you support partial-birth abortion?

- I support access to reproductive care, including safe and legal abortion care.
- Reproductive health decisions should be between a patient and doctor.
- HHS will continue to follow the law.

Q: The Budget still leaves in place the Weldon Amendment and other abortion riders for other federal programs like IHS or FEHBP. Do you support this?

- The President has made clear that removing barriers to accessing reproductive care is a priority. The budget takes important steps to remove such barriers.
- Ultimately, removing the appropriations policy riders that restrict access to abortion is up to Congress and HHS will continue to enforce/follow the law.

ACA: Short Term Limited Duration Insurance (STLDI) Plans

TALKING POINTS:

- Making sure that all Americans have access to quality, affordable health care is one of the Biden-Harris Administration's top priorities.
- Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it.
- To make sure consumers are protected and understand the health insurance they are buying, the administration has stated its intention to revise the short-term limited duration insurance plan regulation.

QUESTIONS:

Q: Many Americans rely on Short-Term, Limited Duration Insurance plans because they are cheaper and don't come with all the unnecessary coverage mandated by the Affordable Care Act. Choice is so important in driving down the cost of insurance, so why are you committed to getting rid of this choice for consumers?

- Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. STLDI plans are exempt from critical Federal requirements for health insurance such as those contained in the Affordable Care Act. I am focused on expanding access to quality health insurance for all Americans, including ensuring consumers with pre-existing conditions are fully protected.

Q: Junk plans continue to trick consumers into buying their shoddy products. When will the Biden Administration take action to limit the availability of Short-Term, Limited Duration insurance plans?

- Thank you for your work on this issue. You're right. Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. To that end, this administration has stated our intention to propose amendments to the definition of 'short-term, limited-duration insurance' under the Public Health Service Act. At HHS, we are focused on making sure that all Americans have access to quality, affordable health care, and I would be happy to keep working with you on this issue.

ACA - Standardized Plans

TALKING POINTS:

- The Biden-Harris Administration has made it a priority to build on the success of the Affordable Care Act (ACA) by continuing to invest in and strengthen the law.
- Thanks to the American Rescue Plan (ARP) and Inflation Reduction Act (IRA), more people this year continued to qualify for help purchasing quality health coverage with expanded financial assistance, and a record-breaking more than 16.3 million people signed up for high-quality, affordable health insurance through the ACA Marketplaces during the 2023 Marketplace Open Enrollment Period.
- In accordance with President Biden's Executive Order on Promoting Competition in the American Economy, and based on new measures finalized in regulation, we have taken additional steps to further simplify the consumer shopping experience beginning in 2023 by requiring issuers offering Qualified Health Plans on HealthCare.gov to also offer standardized plan options.

QUESTIONS:

Q: There is no one-size-fits-all plan design that meets every enrollee's unique health needs. Won't standardized plans unnecessarily restrict consumers choices?

- Issuers are allowed to offer non-standardized plans.
- Standardized plans do not standardize covered benefits.
- Standardized plans help consumers better express their preferences with their plan selections.
- With standardized maximum out-of-pocket limitations, deductibles, and cost-sharing features, consumers are now able to more easily and meaningfully directly compare plans attributes they most care about, such as premiums, provider networks, prescription drug coverage, and quality ratings when choosing a plan, rather than trying to weigh the impacts of small variations in copays or co-insurance requirements that are unlikely to be known by the consumer.
- These standardized plan options also expand the availability of coverage for services before consumers meet their deductibles (including for prescription drugs at the generic and preferred brand tiers at most metal levels), which makes it easier to access important services.

Q: Why is HHS proposing to limit consumer choice in the 2024 Payment Notice? Why do you want to eliminate plan options?

- In the 2024 Payment Notice proposed rule, HHS proposed to limit the number of non-standard plans that marketplace issuers can offer up to two non-standardized plan options per product network type and metal level (excluding catastrophic plans), in any service area for 2024 and later years.

- The average number of plans available to consumers on the Marketplace has increased from 25.9 in 2019 to 113.6 in 2023 – a more than fourfold increase in just four years.
- A large body of research indicates that having this excessive rate of plan proliferation increases the risk of plan choice overload, which limits consumers' ability to make a meaningful selection when comparing plan offerings and increases the risk of suboptimal plan selection – and thus unexpected financial harm for consumers who can least afford it.
- The marketplace is made up of very active consumers. For example, each year, approximately 75% of returning consumers come in to shop and actively select their plans.
- In the 2024 Payment Notice proposed rule, we sought comment on this and other issues related to simplifying plan choice, and we are currently reviewing these as we work to develop a final rule.

Alzheimer's Drug Coverage

Talking Points:

- We lived [through] this, my wife and her siblings and their families. We became caregivers.
- Alzheimer's disease is a devastating illness that affects millions of Americans and their families. HHS is committed to helping people get timely access to treatments and improving care for people with Alzheimer's disease and their families.
- When evaluating new treatments for Medicare coverage, CMS is required to examine whether a medication is *reasonable and necessary*.
- There has not been an Alzheimer's treatment approved by the FDA on the basis of clinical benefit.
- Under the current coverage pathway, people with Medicare can access newly FDA-approved Alzheimer's medications through clinical trials.
- This allows people with early-stage Alzheimer's disease to access these drugs through Medicare, while additional evidence on the treatments' effectiveness in real-world settings is gathered.
- CMS will expeditiously review any new evidence that becomes available that could lead to a reconsideration and change in the current coverage framework.

If pressed on FDA vs. CMS decisions:

- FDA and CMS have different legal authorities to use when considering product approvals, for FDA, and coverage, for CMS. The FDA makes approval decisions based on whether a product is safe and effective while CMS makes coverage decisions based on whether something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- These two processes are separate and run independently by the two agencies. Importantly, however – unlike traditional approval – FDA's accelerated approval pathway does not require finding that a new product demonstrates clinical benefit based on a clinical measure (e.g. how a patient feels or functions) but instead on the effect on a surrogate endpoint that FDA determined reasonably likely to predict clinical benefit; in other words, granting accelerated approval does not provide CMS with absolute certainty that there will be a clinical benefit.

QUESTIONS:

Q: Why did CMS deny the Alzheimer's Association's request for an NCD consideration?

- There has not been an Alzheimer's treatment approved by the FDA on the basis of clinical benefit.

- CMS issued a Federal Register notice regarding the necessary criteria for a reconsideration. As these criteria were not met as of the time of the request, CMS denied Alzheimer's Association's request for an NCD reconsideration.
- CMS will continue to monitor the evidence and engage in discussions with all interested parties.
- CMS is committed to reviewing evidence supporting an NCD reconsideration.

Q: What are the differences in coverage decisions by Medicare for Aduhelm and lecanemab?

- There are no differences in the coverage decisions for Aduhelm and lecanemab.
- Currently, both Aduhelm and lecanemab have received accelerated approval from the FDA.
- If FDA approves Aduhelm, lecanemab, or any other antiamyloid mAb based on a validated measure of clinical benefit, broader coverage using the current framework under Coverage with Evidence Development, would be available on the same day.

Q: Doesn't CMS believe the FDA does a good job? Why is CMS rethinking what FDA already decided?

- The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies.
- The FDA determines whether to approve a new medical product based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use.
- CMS can conduct its own independent review to determine whether an item or service should be covered nationally by Medicare, including examining whether it is reasonable and necessary for use in the Medicare population.

Q: Why is CMS continuing to refuse to cover new Alzheimer's drugs that have been approved by FDA and are now being covered by other federal programs including the Department of Veterans Affairs?

- It is our understanding that the U.S. Department of Veterans Affairs has issued important exclusion and inclusion criteria for its own coverage of this drug using statutory authorities that are different from what Medicare uses. By statute, CMS is required to make coverage decisions based on whether something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- ***If pressed:*** Because of the early evidence and the immense burden of this devastating disease on the Medicare population, the Medicare National Coverage Determination (NCD) provides coverage with evidence development to support rigorous studies to help

answer whether this drug improves health outcomes for patients, and includes a coverage pathway for broader access to these drugs if they receive FDA traditional approval.

Q: When will CMS reconsider this national coverage determination (NCD) to determine whether these treatments/drugs are reasonable and necessary? How long would it take to reconsider this NCD?

- If new evidence emerges that addresses all outstanding questions, as outlined in the NCD, CMS will move swiftly to review and consider whether a reconsideration is warranted.
- ***IF PRESSED ABOUT THE NCD PROCESS:*** In the case of the Alzheimer's accelerated approvals, CMS determined a national coverage determination was needed because the current evidence shows that, while there may be the potential for clinical benefit, there is also the potential for serious harm to patients. (This harm may range from headaches, dizziness, and falls, to other potentially serious complications such as brain bleeds.)

Q: Why was the NCD process applied to this drug and not to other accelerated approvals for oncology drugs, which also have risks?

- CMS follows a long-standing process developed by Congress to determine whether a medical item or service (e.g., device, drug, preventive service) is reasonable and necessary for the diagnosis of and/or treatment of an illness or injury in the Medicare population.

Q: Have you used the NCD process before for other drugs?

- The NCD process is defined in statute (section 1862(l) of the Social Security Act) and is generally how Medicare considers requests for coverage of new items and services. One recent example of CMS's use of the NCD process is for coverage of CAR T-cell therapies.

Q: Has CMS used the coverage with evidence development determination for other drugs or devices?

- Yes, CMS has finalized over 20 coverage with evidence development (CED) NCDs.

ARPA-H

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
ARPA-H	1500	2500	+1000
Total Program Level	1500	2500	+1000

TALKING POINTS:

- The FY 2024 request for ARPA-H includes \$2.5 billion, an increase of +\$1 billion, to build on the success of the agency and continue progress towards achieving the President's vision.
 - The requested funding will support the recruitment of additional Program Managers and will support projects in key technical focus areas to drive transformational innovation in health and speed the application and implementation of health breakthroughs.
- We are thankful to Congress for permanently authorizing ARPA-H and for the work that Dr. Wegrzyn has done since arriving in October. One of the authorities bestowed on the agency by Congress allows them to actively recruit the best minds to tackle the hardest problems in health. ARPA-H will continue to aggressively recruit talented program managers and build a portfolio of programs across the health innovation landscape.
- ARPA-H now has its first technical team leaders in place, and they anticipate hiring approximately 15 Program Managers by the end of the year. Looking into FY 2024, the agency anticipates doubling the number of Program Managers and programs.

QUESTIONS:

- **Q: Where will ARPA-H be located?**
- ARPA-H recently announced their intention to establish sites in three different geographic locations, in accordance with legislation.
- In order to fulfill the agency's mission and the President's vision, ARPA-H must seek the best ideas from all over the country, and serve all Americans, wherever they may be.
- Unfortunately, access to healthcare and innovation can be challenging for Americans, depending on the geography where they are located.
- ARPA-H embraces the opportunity to expand beyond a single location, and intends to use the three sites to accelerate transformational breakthroughs in health by directly connecting ARPA-H with stakeholders, customers, investors, and transition partners.

- The first site will focus on stakeholders and operations and will be established in the Washington, DC area. This will put ARPA-H near key stakeholders, Congress, HHS, CMS, FDA, NIH, the White House, and other federal partners that are essential to their mission.
- Having a location near the majority of our nation's regulatory and legislative partners is crucial.
- In addition to this location, ARPA-H will also be seeking proposals to identify two sites in different regions of the U.S.
- The remaining two sites will serve as hubs, forming the foundation of a hub-and-spoke health innovation network, which will feature numerous spokes across the United States.
- Selection for these remaining two sites will be through an open and competitive process open to any geography in the U.S.
- ARPA-H will not compete the location of the Stakeholder and Operations hub site, but will rely on standard GSA and leasing processes to identify a suitable site.
- ARPA-H will have a nationwide network and part of that network will be in D.C. it is only one of their sites, they will have 3 hubs total each with important roles to fill for the agency.
- No matter where the agency is physically located, its funding will support the best and brightest ideas across the country.

Q: ARPA-H has received \$2.5 billion over the last two fiscal years, we are concerned they will not be able to obligate such an increase, are you confident they will be able to?

- The Department and the Administration fully supports achieving the President's vision for ARPA-H and realizing transformational change and accelerating health outcomes for everyone. Since Dr. Wegrzyn was sworn in as the inaugural director in October, the agency has made tremendous progress. Congress permanently authorized the agency and provided a +50% increase in appropriated funding for its second year in existence. During the first quarter 2023, ARPA-H hired their first program managers and expect programs to begin shortly. The agency has already established operations across all functional areas, hired more than 100 professionals with extensive experience across the health, science, and technology landscape, and met with hundreds of stakeholders from patient advocates to providers to investors. The agency has done all this in just a few months and is in a place where they are ready to hit the ground running to achieve their mission.

Q: How will ARPA-H stay independent from NIH?

- ARPA-H and NIH are complements with one another and both are members of the health innovation ecosystem. ARPA-H and NIH funding is invested in different types of innovation. ARPA-H looks to address health problems that cannot be readily

accomplished through traditional research or commercial activity. Both agencies have the goal of improving the health of everyone but will achieve that with different methods.

- It is also important to note that ARPA-H is a stand-alone entity and is not a NIH Institute or Center, and will not be located on the NIH Campus. While the Consolidated Appropriations Act of 2023 places ARPA-H within the NIH, the ARPA-H Director reports directly to me and the ARPA-H budget is also separate from NIH.

Behavioral Health

(Dollars in Millions) Discretionary Funding

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	5	5	--
HRSA	2,034	2,500	+466
IHS	394	473	+79
CDC	1,132	1,814	+682
NIH ²	8,199	8,382	+183
SAMHSA	7,518	10,422	+2,904
AHRQ	8	20	+12
CMS (discretionary)	5	8	+3
Total Discretionary Program Level	19,295	26,625	+4,330

¹ The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year.

² The FY 2023 Enacted and FY 2024 amounts are estimates and subject to change as NIH finalizes internal allocations.

TALKING POINTS:

- This budget invests \$4 billion more in discretionary funding in meeting behavioral health needs, including funds to increase access to crisis services and grow the behavioral health workforce.
- Suicide is the second leading cause of death for people between ages 10 and 34. The budget includes \$836 million to the 988 and Behavioral Health Crisis program, an increase of +\$334 million, to ensure capacity for the Lifeline to provide life-saving **crisis services** to the estimated 9 million 988 contacts in 2024.
- The budget invests in the **behavioral health workforce** by supporting an estimated 27,000 total mental health and substance use disorder trainees and providers. Specifically, the budget proposes \$387 million for Behavioral Health Workforce Development Programs, an increase of +\$190 million, to grow the number of behavioral health professionals through training approximately 18,000 behavioral health providers; such as psychiatrists, psychologists, clinical social workers, marriage and family therapists, counselors, and peer support specialists.
- The +\$168 million increase to the Certified Community Behavioral Health Centers program will serve 89,000 more people, providing life-saving, 24/7 care to 400,000 Americans. These services benefit them in real ways such as a documented 74% reduction in mental health hospitalizations and a 31% increase of functioning in everyday life.

- Certified Community Behavioral Health Clinics provide high quality, cost-effective **behavioral health services** when and where patients need them. With \$20.1 billion in Medicaid matching funds over 10 years, the budget converts the existing demonstration into a permanent option.
- Currently, the Certified Community Behavioral Health Centers demonstrations are time-limited, with enhanced federal match ending after the demonstration period. We've seen that states who set up these demonstrations serve more patients and see positive results over time. In the first 8 states to participate in the demonstration, Certified Community Behavioral Health Centers served nearly 54,000 more people in their second demonstration year compared to their first. By making Certified Community Behavioral Health Clinics a permanent program, states can use the program in a sustainable way that works for them.
- The budget improves access to behavioral healthcare in Medicare and the private insurance market by requiring coverage of three behavioral health visits and three physical care visits without cost-sharing.

QUESTIONS:

Q: How does the budget address the youth mental health crisis in the United States?

- We have seen a significant increase in mental health needs among youth, including depression, anxiety, and suicidal ideation. The budget includes investments in several programs addressing youth mental health, including Project AWARE, the National Child Traumatic Stress Network, and the Children's Mental Health Services program.
- The nation's mental health crisis is also disproportionately impacting our most vulnerable youth. In 2021, lesbian, gay, and bisexual youth reported greater levels of poor mental health. The budget request for the 988 Lifeline will support specialized services for LGBTQI+ youth to ensure tailored services for this important population.

Q: Some populations are at higher risk of behavioral health concerns—how does the budget focus investments on communities that need it most?

- Suicide risk is disproportionately high for tribal populations, sexual and gender minorities, middle-aged adults, and veterans. The budget proposes a significant increase for the 988 Lifeline, which includes supports for LGBTQI+ youth and services for Spanish speakers. The budget also includes an increase within the Indian Health Service to provide services to American Indian and Alaska Native patients, including suicide prevention, treatment for substance use disorder, and both in person and tele-behavioral health services.
- Individuals with a mental illness are also more likely to experience homelessness than those without mental illness, and they experience homelessness longer than the rest of the homeless population. The budget proposes to provide \$110 million for SAMHSA's

Projects for Assistance in Transition from Homelessness program, an increase of +\$43 million above FY 2023 enacted, to expand the number of communities served and substantially increase the number of participating providers, resulting in 212,000 individuals contacted and 119,000 individuals enrolled in FY 2024.

Q: To improve access to care, the nation needs more behavioral health providers. How does the budget address this need?

- HHS is committed to advancing the recruitment, training, and supporting a diverse behavioral health workforce. The budget includes \$37 million for SAMHSA's Minority Fellowship Programs, an increase of \$17 million over FY 2023 enacted, to almost double the number of fellows. The budget proposal includes a new service requirement to ensure Fellowship participants are supporting communities in need. The budget also proposes historic investments in HRSA to support further expansion of the behavioral health workforce.

Q: How does the budget improve mental health parity?

- Medicare beneficiaries with mental health and substance use disorders are just as deserving of protection and care as those with medical, physical, or surgical needs. Unlike most private and employer-based insurance and Medicaid plans, Medicare is not subject to the 2008 Mental Health Parity and Addiction Equity Act, which requires health plans that offer mental health and substance use disorder benefits to provide coverage on par with the medical and surgical benefits they offer. Applying parity to Medicare will ensure that Medicare behavioral health benefits do not face greater limitations relative to medical and surgical benefits. The budget invests \$1.2 billion in HHS funding to strengthens mental health parity on the private insurance market by requiring all plans to cover mental health and substance use disorder services, eliminating loopholes that have resulted in disparate coverage practices, and requiring plans to cover three behavioral care visits with no beneficiary cost sharing.

Q: How much will Americans save in copayments from requiring three behavioral health visits without cost-sharing?

- The amount of money that individuals will save depends on the benefit and cost-sharing structure of the plan that the individual is enrolled in. For example, an individual enrolled in a silver-level Marketplace plan with an applicable co-payment for behavioral health services will save an average of \$34 per visit (\$102 for first three visits). An individual enrolled in a plan where the deductible must be met before cost-sharing limits apply may save an average of \$100-200 per visit (\$300-600 for first three visits).
- Coinsurance for a typical Medicare behavioral health visit would be \$15 to \$20.

Q: How does the budget improve behavioral health integration?

- Behavioral investments throughout the budget support integration efforts. Just to name a few specific proposals:
 - \$103 million, an increase of \$47 million, for SAMHSA's Primary and Behavioral Health Care Integration program, to advance the integration of physical and behavioral health care using evidence-based models of care.
 - \$90 million, an increase of \$52 million, to allow to CDC scale up the *What Works in Schools* program from 28 up to 75 local education agencies nationwide. This program strengthens the integrated delivery of mental health promotion and treatment interventions to students and families across a range of care settings.
 - \$5 million in funding for AHRQ to research and understand how to scale existing Local Integrated Care Network models – which provide behavioral health support systems for primary care practices.

Bipartisan Safer Communities Act (BSCA)

TALKING POINTS:

- The Bipartisan Safer Communities Act (BSCA) which was signed into law by President Biden last summer strengthens the mental health care system, school safety programs, and gun safety laws – further advancing the President's whole-of-government mental health strategy, which he launched as part of his Unity Agenda.
- HHS has worked hard to get funding in the bill out the door as quickly as possible.
 - See Grant Award funding below.

If asked about grant funding:

- BSCA provided \$800 million in funding to SAMHSA for behavioral health grants, including:
 - \$250 million for Community Mental Health Services Block Grants,
 - \$240 million for Project Advancing Wellness and Resiliency in Education (Project AWARE),
 - \$120 million for Mental Health Awareness Training,
 - \$40 million for the National Child Traumatic Stress Network
 - \$150 million for the new 988 Suicide & Crisis Lifeline.
- All BSCA funding for the 988 Lifeline has been obligated.
- HRSA announced \$60 million in Primary Care Training and Enhancement awards and \$15 million in Pediatric Mental Health Care Access awards, with more to come.

If asked future opportunities:

- The law includes a nationwide expansion of Certified Community Behavioral Health Clinics (CCBHCS).
 - We recently awarded planning grants to 15 states.
 - After one year of state planning, they are expected to apply to participate in the demonstration program funded through Medicaid, and 10 states will be selected to start as soon as July 2024.
 - Ultimately, every state will have the opportunity to participate.
- CMS is working to:
 - Award \$50 million in grants towards implementing, enhancing, or expanding the provision of assistance through school-based entities under Medicaid or CHIP.
 - Provide guidance and technical assistance on Medicaid telehealth services.
 - Review State Implementation of Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services.

Cancer Moonshot

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	2	50	+48
HRSA	11	21	+10
IHS ²	--	108	+108
CDC	656	839	+183
NIH ³	216	716	+500
Total Program Level	885	1,733	+849

1/ The FY 2023 President's Budget proposed a one-time increase of \$20 million for FDA's cancer moonshot activities. The funds were requested with three-year availability. The House mark provided \$7M as an annual base increase and not as a one-time increase.

2/ The FY 2023 Budget and all FY 2024 columnus propose IHS funding as mandatory.

3/ Funding level reflects authorized CURES and non-CURES funding

TALKING POINTS:

- The reignited Cancer Moonshot includes the specific aim of **cutting the cancer mortality rate in half within 25 years.**
- We will build upon the successes of the foundational Moonshot programs (e.g., improving immunotherapy for adult and pediatric cancers, exploring drug resistance, boosting efforts for collecting/sharing cancer data) to continue to improve prevention, diagnosis and treatment outcomes and quality of life for all people.
- In February we hit the one-year anniversary of President Biden's Cancer Moonshot Initiative. Key efforts to date include:
 - **Increasing Cancer Screenings in Underserved Communities:** In February HRSA awarded nearly **\$11 million to 22 health centers** to improve access to life-saving cancer screenings and early detection services for underserved communities. These awards double support for an initiative launched last year by the Biden-Harris Administration through which HRSA-funded health centers are working to close the cancer screening gap and decrease the impact of preventable cancers.
 - **Expanding NCI Clinical Trials:** This will allow the development of new and improved treatment options for people with cancer through novel clinical trials; We will also ensure that cancer clinical trials are available in the communities in which people live and receive their care.
 - **Establishing comprehensive infrastructure to share and process cancer data** and enabling the fullest possible use of all forms of research data while protecting patient privacy.

QUESTIONS:

Q: What is different about investments this time?

- The Obama-Biden administration delivered significant investments in cancer research activities that accelerated progress of prevention, diagnosis, and treatment programs.
- Because of this foundation, this Administration is now able to set the goal of reducing the death rate from cancer by at least 50 percent over the next 25 years.
- The President has now emphasized the need to focus on patients and their families living with cancer, a focus of HHS investments. We will continue to make foundational investments in cancer research, prevention, and care.
- We are investing in outreach and education efforts with \$20 million to support HRSA-funded health centers in reaching underserved communities and part of FDA's \$50 million Cancer Moonshot funds dedicated to research and education.

Q: What is NIH doing to diversify Clinical Trials?

- NIH remains dedicated to ensuring inclusion throughout its supported clinical research activities.
- NIH has longstanding policies to ensure appropriate inclusion of women and minorities, and individuals across the lifespan in clinical research.
- NIH has made several strides to ensure that clinical trials reach as many communities as possible and that we are held accountable for continuing these efforts. For example,
 - 29% of U.S. participants in NIH-funded clinical research identified as members of a racial or ethnic minority group (FY22 74% identified as white, 1.3% unknown, unreported).
 - Female participants represented 52%.
 - Children under 18 years represented 14% and adults older than 65 represented 21%.
- To facilitate greater diversity in clinical trials, it is crucial to establish and facilitate trust between the research community and local community members and leaders.
 - Lessons learned from the Community Engagement Alliance (CEAL) program which helped engage communities around COVID-19 are being applied to broader research contexts.

Q: What are you doing to address multi-cancer early detection?

- One year ago, President Biden reignited the Cancer Moonshot and set new national goals to cut the death rate from cancer by at least 50% over the next 25 years and improve the experience of people and their families living with and surviving cancer.
- At HHS, we are doing all we can to make cancer prevention and screening services accessible to everyone in the United States, including taking action to address the estimated 9.5 million cancer screenings missed during the pandemic.
- I look forward to hearing more from you about increasing access to preventive health services, particularly for cancer prevention.

- HHS always appreciates the opportunity to provide technical assistance to Congress on important health care issues.

CCBHCs
(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Certified Community Behavioral Health Clinics (SAMHSA)	\$385	\$553	+\$168
Total Program Level (Discretionary Only)	\$385	\$553	+\$168

TALKING POINTS:

- The Certified Community Behavioral Health Clinic (CCBHC) model is designed to ensure access to coordinated and comprehensive behavioral health care. CCBHCs are required to serve anyone who requests care for mental health or substance use, regardless of their ability to pay, place of residence, or age - including developmentally appropriate care for children and youth.
- The Bipartisan Safer Communities Act provided funding to give every state the opportunity to participate in CCBHC demonstration program already successfully running in nine states. Fifteen states were recently awarded planning grant funding from the law, with more to come.
- The FY 2024 Budget converts the CCBHC demonstration to a permanent program and proposes a +\$168 million increase for SAMHSA's CCBHC program.
- This investment into CCBHCs underscores the Biden-Harris Administration's commitment to strengthening the mental health of all Americans, including people living in our nation's most vulnerable communities. Behavioral health is health. Period. There should be no distinction. This investment will bring us closer to that reality.

QUESTIONS:

Q. How are state planning grants different from the CCBHC expansion grant program?

- State planning grants will help states prepare to participate in the CCBHC program funded through Medicaid. SAMHSA's CCBHC Expansion grants are awarded directly to provider organizations.

- The purpose of the provider-level CCBHC Expansion grant is to support clinics to meet the CCBHC certification criteria and mainly support service development and delivery.

Q. How do the state planning grants work?

- States that have completed planning grants will be eligible to apply to participate in the CCBHC Demonstration at the end of the year-long planning grant period.

Q. Can states that received planning grants in FY 2016 apply again in this round?

- States that received planning grants in FY 2016, but were not selected to participate in the Medicaid Demonstration, can re-apply.

Q. How will states be selected for planning grants?

- States' grant applications will be peer-reviewed, scored, and selected based on: statement of need, population of focus, proposed approach, staff and organizational experience, and data collection and performance measurement.

Q. What happens after the planning grant project period ends?

- At the end of the planning grant period, participating states must submit their applications to join the CCBHC Demonstration for a four-year period starting on July 1, 2024.

CDC Moving Forward

TALKING POINTS:

- CDC Director Dr. Rochelle Walensky launched Moving Forward to strengthen CDC by strategically building on lessons learned during the COVID-19 pandemic to break down silos, reduce bureaucracy, and improve accountability.
- This effort will be critical to deliver health information more clearly and quickly to policy makers and American. We're already seeing the benefits of this effort:
 - CDC was the first in the world to produce data showing real-world effectiveness of the JYNNEOS vaccine for mpox.
 - Two public-facing databases went live in April 2022 that provide public health practitioners and the public with critical data about non-fatal overdoses and overdose deaths to tailor interventions in their communities.
- As CDC makes the changes it can internally, we also need help from Congress through funding and new authority to fully deliver on its mission of protecting the health, safety, and security of Americans.

QUESTIONS:

Q: Should Congress Authorize CDC and put in statute a clear organization structure?

- I want to be clear that CDC activities are authorized in the Public Health Service Act.
- Through Moving Forward, CDC has focused on lessons learned and is making important changes to break down silos, reduce bureaucracy, and improve accountability.
- As CDC makes the changes it can internally, we have also identified key policy changes that can only be achieved through Congress.
- My hope is that we can focus on these key areas to find bipartisan solutions to support the health, safety, and security of Americans.

Q: How will the reorganization allow CDC to better serve the American people?

- Reduce bureaucracy and improve accountability.
 - CDC elevated the offices of science, laboratory, and data to be in the Office of the Director.
 - These are cross-cutting offices that provide foundational support and should have direct access to the Office of the Director.
 - CDC combined two centers that supported relationships with jurisdictions, as well as workforce and infrastructure technical assistance.
 - This new center will provide clarity on where STLT should go for technical assistance and strengthen our working relationships with jurisdictions.

- CDC elevated the Center for Preparedness and Response to the Office of the Director.
 - Response activities cut across CDC and are not siloed to one center.

Q: What changes has CDC already made?

- Share science and data faster
 - Improved timeliness of getting science out by reducing internal review times by 50 percent.
 - We were the first country in the world to produce data showing real world effectiveness of JYNNEOS.
- Translate science into practical policy
 - CDC's Overdose Data to Action (OD2A) databases
 - These two, public-facing dashboards include near real-time syndromic data on nonfatal overdoses in emergency departments as well as information on the circumstances and context of overdose deaths. The dashboards allow public health practitioners and members of the public with critical data to tailor interventions in their communities.
- Develop a CDC workforce ready to respond to future threats
 - Established CDC Ready Responder Program.
 - This program, deployed in December, is identifying, training, and assigning staff to response roles, to better serve partner organizations, and protect communities that are most at risk during emergencies.

Q: What does CDC need from Congress?

- A modernized data authority to receive and share back data more quickly. This allows CDC to forecast, track, and prevent the spread of emerging issues.
- Workforce authorities – numerous workforce authorities to build and support CDC's workforce to quickly respond and to sustain that response through a public health emergency.
 - Direct Hire
 - Overtime and danger pay
 - Tax waiver for loan repayment
 - Non-competitive conversion for term hires
 - Ready Response – budget flexibility to have a cadre of responders ready to go at a moment's notice.
- Vaccines for Adults
 - We must leverage what we built for COVID to create a sustainable adult vaccine infrastructure to be better prepared for the next pandemic and to improve vaccine access and equity across our population.

Countermeasures Injury Compensation Program (CICP)/Vaccine Injury Compensation Program (VICP)

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		President's Budget	+/- FY 2023 Enacted
Countermeasures Injury Compensation Program	7,000	15,000	+8,000
Vaccine Injury Compensation:			
Vaccine Injury Compensation Trust Fund (HRSA Claims)	256,370	261,497	+5,127
VICTF Direct Operations - HRSA	15,200	26,200	+11,000
Subtotal, Vaccine Injury Compensation	271,570	287,697	+16,127

TALKING POINTS:

- First, COVID-19 vaccines are the most safe and effective way to prevent yourself from severe harm and death from COVID-19.
- Second, HHS is actively working to process claims as **quickly** as possible, in compliance with the relatively **high standard** set out in statute that must be met for compensation.
- While the Agency has worked hard to hire additional medical reviewers and is implementing key process improvements, the additional resources in the Budget will help support the work to **address the backlog**.
- The President's Budget request is a step in the right direction.

QUESTIONS:

Q: If we meet your budget request this year, will it resolve the current CICP backlog, and how quickly? What else is needed?

- Last year's Budget proposed \$15 million to review additional CICP claims and compensate eligible individuals. However, only \$7 million was appropriated which supported the hiring of additional staff.
- The additional funds we are requesting this year would help expedite the processing of claims by hiring additional medical reviewers, streamline the review process to be more claimant friendly, and compensate claims.

Q: What is the impact of the end of the COVID-19 Public Health Emergency on COVID-19 claims in the CICP?

- The PREP Act Declaration for Medical Countermeasures against COVID-19 currently extends through October 1, 2024

Climate Health and Environmental Justice

TALKING POINTS:

- HHS is committed to addressing the impact of climate change on Americans' health and promoting climate resilience in the health care sector.
- As extreme heat events and hurricanes become more intense due to climate change, we need to understand and mitigate these impacts so our health systems are prepared.
- We also must make sure we are targeting our resources equitably to ensure that benefits accrue to communities that have been marginalized or overburdened by climate and environmental health hazards.

QUESTIONS:

Q: Why does HHS need an Office working on climate change? Doesn't EPA have health in their mission?

- Climate change is affecting our health today and putting lives at risk.
- Extreme heat events are predicted to happen more often and last longer due to our changing climate.
 - FACTOID: This past summer in Maricopa County, Arizona, [378 people died from heat](#). That number was up from the previous summer when [338 people died from heat](#).
- Hurricanes are becoming more intense due to climate change.
 - FACTOID: Hurricane Ian led to [at least 144 deaths](#) in Florida when it hit in September 2022, making it one of the worst hurricanes in state history. Two-thirds of the 144 confirmed deaths were people aged 65 years and older.
- While EPA has a role in protecting the environment and promoting public health, HHS is responsible for ensuring the resilience of our nation's healthcare systems.

Q: Is creating a new Office focused on climate change going to further strain our already overwhelmed healthcare systems?

- The recent heat dome event in Oregon and Washington and Hurricanes Ida, Ian, and Michael in Florida have shown us that the increasingly frequent and severe weather events caused by climate change are already causing hospitals to close and leading to illness and death.
 - FACTOID: Hurricane Ida [forced three damaged hospitals in Southeast Louisiana to evacuate 160+ patients](#). A massive failure of the electric grid forced hospitals to operate on generator power and rely on water from on-site wells.
- Failing to acknowledge and address this reality will only cause more harm to our most vulnerable citizens.

- The Office of Climate Change and Health Equity is already providing technical assistance and connections to existing federal resources to help health systems manage their growing risks associated with climate change.

Q: Congress hasn't given HHS any authority to regulate greenhouse emissions...why are you forcing Hospitals to reduce their emissions?

- The US health sector is responsible for roughly 8.5% of the nation's total greenhouse gas emissions. We are excited that over 830 hospitals have signed the White House/HHS Health Sector Climate Pledge to: cut their greenhouse gas emissions by 50% by 2030 and achieve net-zero emissions by 2050.
- With that said, the pledges made are voluntary; the organizations that signed this pledge are not obligated to report data on their progress to the federal government in association with this pledge.
- As I said from the moment we launched the Office, nothing is off the table when it comes to the policy levers the Department will deploy going forward. We will consider everything at our disposal and that could include regulatory action in the future.

Q: Why does HHS need its own Office of Environmental Justice? Aren't these issues covered under EPA and other departments?

- Protecting our nation's health from environmental harms requires working in partnership across government.
- Studies demonstrate that people of color and disadvantaged, vulnerable, low-income, marginalized, and indigenous populations are disproportionately burdened by environmental hazards.
- These populations are often exposed to unhealthy land uses, poor air and water quality, dilapidated housing, lead exposure, and other environmental health threats that drive health disparities.
- HHS has a key role in providing public health leadership and focusing human services to help meet the needs of these communities.
- One more point for a tangible example:
 - We're using the new Environmental Justice Index, developed by CDC/ATSDR, to show the cumulative burden of social, environmental, and underlying health factors in neighborhoods that would bear the brunt of transportation projects. For example, a tolling program in Manhattan that could increase air pollution in the Bronx should maximize health protections for already vulnerable communities.

Q: Our understanding is that both the Office of Climate Change and Health Equity and its Environmental Justice division have already been established. Congress did not appropriate funding for this Office in FYs 21, 22, or 23. From what resources has HHS funded the operations of this Office?

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- I have determined that based on the importance of this work, my Secretarial Initiatives and Innovations funding would be used to support this work while we await dedicated Congressional funding.

CMMI /Innovation Center

TALKING POINTS:

- Innovation in health care should be designed for the people it serves; its success should be measured by how well it improves health, experience, and affordability of care.
- The Innovation Center, with its federal and community partners, has started building the foundation toward a health system that achieves equitable outcomes through high-quality, affordable, person-centered care.

New Coordinated Care Models

- The Innovation Center has announced the:
 - Enhancing Oncology Model (EOM), which aims to bring enhanced services and coordinated care to people with cancer; and
 - The redesigned (ACO REACH) Model, which aims to increase access to team-based, coordinated care, and improve the beneficiary experience, especially for underserved populations

New Drug Models

- This year, I selected three new models for testing by the CMS Innovation Center to help lower the high cost of drugs, promote accessibility to life-changing drug therapies, and improve quality of care. This report responds to President Biden's Executive Order 14087, "Lowering Prescription Drug Costs for Americans," which complements the historic provisions in the Inflation Reduction Act of 2022 (IRA) that will lower prescription drug costs.

QUESTIONS:

Executive Order

Q: Why is CMS maligning drugs that rely on surrogate end points – and the accelerated pathway used by FDA? The drugs approved under this process clearly show pre-clinical benefit.

- The Accelerating Clinical Evidence Model does not change the FDA accelerated approval process. The model simply aims to incentivize timely completion of confirmatory trials.
- Completion of confirmatory trials is important so that everyone has the benefit of better understanding the value of these accelerated approval drugs.
- The Accelerating Clinical Evidence Model will not change FDA's role in determining and assessing whether a drug has met the drug approval standard or whether a confirmatory trial confirms clinical benefit.

Q: Congress just updated the FDA user fee law. Can you tell me more about how CMS proposes to define "too long" for a confirmatory clinical trial to conclude?

- CMS will cooperate with the FDA as we develop this model and will clearly define expectations regarding the completion of clinical trials.

Q: Many plans have copayments less than \$2 on generic drugs currently. Won't this just create upward pressure on all plans to charge \$2, thus increasing copays for beneficiaries?

- This model would encourage plans to expand their current low copay drug offerings and provide beneficiaries access to a standardized list of generics (with copays of no more than \$2) across participating plans. Historically market dynamics have shown Part D sponsors want to offer competitive cost-sharing.

ACO REACH

Q: Concerns have been raised regarding the participation of organizations with known histories of fraud and abuse in the ACO REACH Model. How will CMS prevent these organizations from engaging in fraud and abuse under the ACO REACH Model?

- CMS conducts a comprehensive set of vetting, monitoring, auditing, and analytic activities under the ACO REACH Model aimed at protecting beneficiaries, and the fiscal health of the Medicare program. Each model participant is required to cooperate with CMS's monitoring and auditing activities, and each must require its downstream providers and suppliers to cooperate with those activities as well.
- Failure to comply with model requirements is addressed through a set of escalating remedial actions that include placement on a corrective action plan or, in select instances, termination from the model. In addition, CMS may refer possible violations of federal laws by model participants to other federal agencies, such as the Department of Justice.

Q: Are any of the REACH ACOs health insurers or Private Equity / Venture Capital backed? If so, how many?

- Based on available data, CMS estimates that less than 10% of REACH ACOs are affiliated with a parent organization that also operates health insurance plans.
- To bring greater transparency to this program, CMS committed to publicly releasing ownership data on its participants and did so earlier this year.
- CMS also made requirements of participants' governing boards, ensuring 75% of the board is made up of doctors and health care providers and requiring participation by beneficiaries and their advocates.

Q: Participants in the Global and Professional Direct Contracting Model were able to transition to ACO REACH without having to go through the applicant screening process. Did CMS review existing participants against the new applicant screening process?

- To be able to transition to the ACO REACH Model, Global and Professional Direct Contracting Model participants were assessed on the status of their compliance the current model requirements.
- They were also required to submit additional documentation consistent with what CMS required of ACO REACH Model applicants, specifically ownership, leadership, and governing board documentation that was used as part of a comprehensive vetting process.

Conscience Protections

TALKING POINTS:

- HHS has long enforced federal conscience and religious nondiscrimination laws for many decades.
- HHS will continue to follow the law and enforce it, which importantly includes religious freedom and conscience laws.

QUESTIONS:

Q: Does OCR's recent reorganization mean OCR will abandon enforcing conscience laws and religious freedom protections?

- No. HHS will continue to follow the law and enforce it, which importantly includes religious nondiscrimination and conscience laws.
- The reorganization re-integrates the Office for Civil Rights' expertise in protecting conscience and the free exercise of religion into the overall civil rights responsibilities of the division to bridge an unnecessary separation between these authorities.
- The change restores a holistic approach to civil rights enforcement while also providing more effective use of available staff expertise and resources.

Q: Will the Conscience NPRM be impacted by this reorganization?

- No, the reorganization will not impact OCR's work on the Conscience NPRM.
- This NPRM proposes to restore the longstanding process for the handling of conscience complaints and provide additional safeguards against conscience and religious discrimination.
- OCR is currently reviewing comments received earlier this month.

Q: What is the breakdown of OCR's complaints by authorities?

- OCR's caseload has multiplied in recent years. In CY 2021, OCR received approximately 51,280 complaints, 27% alleged violations of civil rights, 7% alleged violations of conscience/religious freedom (either singularly or in combination with other civil rights allegations), and 66% alleged violations of health information privacy and security laws. HIPAA violations make up the majority of complaints received by OCR and this will only continue to grow.

Q: What outcomes does HHS hope to achieve through this realignment?

- OCR enforces 55 statutory authorities. OCR realigned the Division's activities to better meet its statutory mandates, enforce the law and be responsive to the growing needs of the public in health information privacy, data, and cybersecurity, conscience protections, and civil rights. These changes move OCR from a more siloed operation to one that

utilizes the agency's skill set and resources more effectively. Specifically, OCR reorganized the responsibilities of the current Health Information Privacy, Operations and Resources, Civil Rights and the Conscience and Religious Freedom divisions into new functional crosscutting areas: for Policy, Strategic Planning, and Enforcement where staff work in their areas of expertise based on skill set to drive greater implementation and enforcement of the law.

COVID Supplemental Funding Balances

(Dollars in Billions)

Supplemental	Enacted	Remaining Balance	Percent Remaining
Coronavirus Preparedness and Response Supplemental	\$6.5	\$0.5	7%
Families First Coronavirus Response	\$1.3	\$0	0%
Coronavirus Aid, Relief, and Economic Security	\$142.5	\$3.1	2%
Paycheck Protection Program and Health Care Enhancement	\$100	\$7.2	7%
Coronavirus Response and Relief	\$73.8	\$1.3	2%
American Rescue Plan	\$160.5	\$17.3	11%
Total Supplemental Funding	\$484.6	\$29.5	6%

TALKING POINTS:

- Since 2020, we've delivered over 294 million vaccines, collaborated with the U.S. Postal Service to distribute more than 670 million at-home tests, administered over 22 million vaccine doses at our HRSA-supported health centers, and continuously reviewed, updated, and communicated new guidance to the public and our health care industry partners.
- As of March 6, HHS has obligated 94% of the COVID supplemental funding received; that's over \$455 billion to purchase vaccines and other critical medicines, reimburse providers for COVID care, distribute tests, conduct research, and otherwise protect the Nation's health.
- HHS has approximately \$29.5 billion left unobligated in COVID supplemental funding – only 6% of the of total we've received – with the remainder planned to support critical projects and in the process of execution.
- HHS's goal for these balances is the same goal we have for the FY 2024 budget: move forward from the COVID-19 pandemic, and look to the future by investing heavily in pandemic preparedness. We must do everything we can now to be ready for the future.

QUESTIONS:

Q: You'll be ending the Public Health Emergency for COVID in May. Will you be returning COVID funding balances to Congress now that there's no emergency?

- All balances are intended for critical, ongoing activities such as, monitoring the safety and efficacy of vaccines, conducting multi-year research and development on new medical countermeasures, and sustaining stockpiled countermeasures and protective equipment for the next emergency.
- These investments also support our public health preparedness infrastructure. CDC continues to invest supplemental funding at the federal, state and local levels to build our nation's capacity to respond to COVID-19, but also for other, future threats.

- We've seen a consequential impacts from the dollars spent to far on the response. Since 2020, we've delivered over 294 million vaccines, collaborated with the U.S. Postal Service to distribute more than 670 million at-home tests, administered over 22 million vaccine doses at our HRSA-supported health centers, and continuously reviewed, updated, and communicated new guidance to the public and our industry partners.

Q: COVID revealed the ways in which the United States was not ready for an infectious disease threat of this magnitude. What are you doing to ensure we can be better prepared for future biological threats and infectious disease outbreaks?

- We need to do more to prepare against potential biological threats – the question is “when”, not “if” the next pandemic threat will emerge.
- That's why my FY 2024 budget includes a \$20 billion plan to transform the way we prepare for and respond to pandemic and other biological threats. The looming avian influenza threat is exactly the kind of threat we could have been preparing for in advance – but we need funding to do so.
- The Budget also includes discretionary investments to preparedness complementary to the mandatory proposal. This includes \$400 million in new funding at ASPR to continuously invest in long-term pandemic preparedness capabilities, over \$1 billion for BARDA, \$995 million for the Strategic National Stockpile, and other strategic investments at CDC, FDA, and NIH.
- The budget also includes a suite of legislative proposals intended to give HHS and its agencies better authorities to prepare for and respond to emergencies. We learned many lessons during COVID, mpox, and other recent emergencies, but we need Congress's help to implement these changes.

Q: If you have almost \$30 billion dollars left, and my hospital that your agency denied Provider Relief Funds to is on the verge of closing due to lack of funds—why can't you re-open the PRF and give my hospital the funding it needs to stay open?

- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding —96% of all funding, with the remaining 4% in the process of being executed.
- HHS has allocated resources to reimburse health care providers for the cost of COVID-related health care through the Provider Relief Fund program. HRSA conducts a thorough, multi-step process to evaluate and verify provider claims and requests for reconsiderations. While most funds have been obligated, in some instances, HRSA's process is not yet complete. Congress made these funds available until expended.
- HHS obligates PRF funds as payments are made.

Q: Why are you using PRF dollars for vaccines and testing if you have \$30 billion left?

- All Covid supplemental funding has been allocated in alignment with the purposes of the appropriations. While approximately \$30 billion is unobligated, all of this amount is already allocated to critical needs, mostly to support actively ongoing projects, including for Provider Relief Fund payments. All remaining funding cannot be obligated at once – many of the ongoing projects, like clinical trials, require us to continue to provide funding over time.

Q: If you have \$30 billion why did you close the Uninsured Program?

- HHS is committed to doing everything it can to ensure that the uninsured can receive the lifesaving care, vaccines, and therapeutics that they need. The funding for the uninsured program has been exhausted, a fact we alerted Congress to many times as we requested additional COVID supplemental funds
- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding, which is nearly all of the PRF funding we received.
- While we do have \$30 billion in unobligated funding, all of this funding is allocated for critical needs. Additionally, not all unobligated funding would be legally available to support the Uninsured Program.
- Further, my administration is committed to insuring the un- and under-insured in this country, which is why the national uninsured rate hit an all-time low of 8% in 2022. To this same end, I call on the remaining 10 states to follow North Carolina's lead and expand their Medicaid programs.

Q: COVID-19 Tests.gov website shut down in 2022 due to a lack of funds, but now you have \$30 billion. Please explain this to me?

- Our groundbreaking partnership with the US Postal Service distributed more than 670 million at-home COVID-19 tests to Americans all across the country. By making tests freely available through multiple means, as well as life-saving vaccines and therapeutics, we've done everything we can to tackle the COVID-19 pandemic.
- HHS has approximately \$29.5 billion left unobligated in COVID supplemental funding – only 6% of the of total we've received – with the remainder planned to support critical projects and in the process of execution.
- HHS could not continue to distribute tests through covid.gov/tests with limited funding. The HHS response to COVID-19 is broader than just providing free tests, and we had to allocate resources to where they were needed most.

COVID - Long COVID

TALKING POINTS:

FY 2024 Budget Talking Points

- The Administration continues to invest in delivering high-quality care for individuals experience Long COVID, making services and supports available, and advancing the nation's understanding of Long COVID.
- To help improve Long COVID care, the budget proposes \$130 million in new resources to HRSA to:
 - Fund Long COVID Integrated Diagnostics and Care Units, which will provide integrated multispecialty evaluation and care for uninsured patients with Long COVID, including through telemedicine.
 - Support Provider Training, Capacity Building and Consultation, serving to provide primary care providers with the latest knowledge about Long COVID diagnostics and treatment.
- Additionally, the FY 2024 budget invests \$19 million, an increase of \$9 million, to continue AHRQ's work to ensure health care delivery systems are prepared to provide patient-centered, coordinated care. Long COVID cases can be complex, affecting multiple organ systems and touch multiple specialties.

General Long COVID Talking Points

- Most people who have COVID-19 recover quickly and completely, but some people continue to experience new or re-occurring symptoms or conditions for weeks, months or even years after the initial infection.
- We must build on the lessons learned from other infection associated chronic illness, such as ME/CFS or dysautonomia.
- The end of the declared Public Health Emergency will not signal the end of the COVID-19 pandemic. Long after the more immediate effects of the pandemic, the longer-term impacts on the health of the nation will continue for years to come. The scale of Long COVID morbidity and mortality and the breadth of its clinical manifestations represent an unprecedented, but not insurmountable, challenge.
- Pandemic preparedness must include planning for post-infectious chronic illness.
- To meet our public health goals there must be continued investment at the federal and community level to meet people in need where they are, and to provide support and services to help them live their healthiest lives.

Federal Government Response to Long COVID

- The U.S. government has been conducting research on Long COVID since 2020 and providing care for individuals with Long COVID within federally supported healthcare systems such as the Veterans Health Administration, Federally Qualified Community

Health Centers, Certified Community Behavioral Health Clinics, and the Indian Health Service.

- o Milestones in the U.S. government response include a call for action on Long COVID in the [Presidential Health Equity Task Force](#), Final Report and Recommendations, released in October 2021, [announcement of the landmark RECOVER study in February 2021](#), and inclusion of Long COVID in the [National COVID-19 Preparedness Plan](#) in March 2022.
- o In April of 2022 President Biden issued the [Memorandum on Addressing the Long-Term Effects of COVID-19](#) instructing the Secretary of Health and Human Services to begin coordinating a government-wide response. Part of that response resulted in the publication of two reports in August 2022. These reports were the product of collaboration among 14 federal departments and were a significant step in orchestrating a government wide response. Together, these reports use a whole-of-government approach and call on the power of public-private partnerships to provide relief for those affected by Long COVID.
- o The [Services and Supports for Longer-Term Impacts of COVID-19](#) Report outlines over 200 federally funded support and services that may be available for individuals experiencing the longer-term effects of COVID-19 in the areas of Long COVID and associated conditions, mental health, substance use, and bereavement.
- o The [National Research Action Plan on Long COVID](#) provides an overview of current U.S. government conducted or funded research and proposes a comprehensive and equitable research strategy to inform our national response to Long COVID.

RECOVER Initiative Talking Points:

- NIH launched the Researching COVID to Enhance Recovery (RECOVER) initiative in December 2021 to define the clinical symptoms, long-term outcomes, underlying biology of Long COVID, and safe and effective therapeutic and preventive interventions.
- NIH RECOVER built the world's largest, most diverse clinical cohort of Long COVID patients across the lifespan. The initiative is patient-centered and is unparalleled in scope, scale, and speed, with integrated analyses of EHR and other real-world data.
- We have learned vital information from RECOVER, including the clinical spectrum in adults and children, risk factors for developing Long COVID or new-onset conditions, the impact of variants and vaccination, and symptom profiles that will enable clinical practitioners to screen for Long COVID.
- RECOVER expects to launch a suite of clinical trials this year that will delve deeper into key symptoms and explore how the virus survives and leads to long-term symptoms. These studies will also help us to understand the underlying biology so we can fine-tune interventions moving forward.

QUESTIONS:

Q: Why haven't we seen results from RECOVER yet? When will those be publicly available?

- RECOVER is moving at an unprecedented quick pace for a study with the comprehensive national scale required to understand and treat a new syndrome. RECOVER is a longitudinal, multifaceted effort which has already yielded results identifying the clinical symptoms in children and adults, risk factors for PASC, the impact of variants and vaccination on disease. In addition to these successes, a suite of clinical trials is expected to be launched in summer 2023 to focus on the symptoms that are most burdensome to daily life and to look at disease mechanisms. Like any clinical trial, we would expect initial results from clinical within a few years, however longitudinal studies inherently require several years if not decades to complete.

Q: When will clinical trials for Long COVID begin? Why is it taking so long?

- To achieve the depth and breadth required to get the answers patients need, we did a great deal of the work on the front end—like developing master protocols—based on everything we know. This is helping us to get to answers faster with data we can depend on and use, and treatments patients can trust.
- RECOVER is launching multiple randomized, comparator-controlled clinical trials for which site recruitments are underway. Through the balance of this year, RECOVER will be testing candidate therapies for symptoms described by patients as being most burdensome. Those protocols are now posted to clinicaltrials.gov.

Q: What is HHS doing to respond to Long COVID?

- Nearly a year ago the Biden Administration issued the Memorandum on Addressing the Long-Term Effects of COVID-19 which tasked me with organizing the Government-Wide Response to the Long-Term Effects of COVID-19. Including the issuance of two reports:
 - o **The Services and Supports for Longer-Term Impacts of COVID-19 Report (Services Report).** The Services Report outlines over 200 federally funded supports and services for individuals experiencing the longer-term effects of COVID-19 in the areas of Long COVID and associated conditions, mental health, substance use, and bereavement.
 - o **The National Research Action Plan on Long COVID (the Research Plan).** The Research Plan outlines over 70 active research programs on Long COVID, including NIH's RECOVER and CDC's INSPIRE, which have helped contribute to the hundreds of publications, with more on the horizon. The Research Plan also proposes a comprehensive and equitable research strategy to inform our national response to Long COVID.
- Starting work in earnest in mid-2021, the U.S. government continues to lead and make advancements in research and provide resources to those affected by Long COVID, recognizing much more must be done to support people experiencing Long COVID and associated conditions.

Q: I hear from constituents that they go to the doctor and nobody believes them and they can't get care. What is HHS doing to fix this?

- Unfortunately, this occurs. While there are many compassionate and competent healthcare providers finding and caring for Long COVID patients, it is a new entity and awareness needs to increase both among the citizenry and healthcare professionals.
- Our whole-of-government coordination efforts to address the long-term effects of COVID-19 has prioritized listening to and learning from those with lived experience, so we can accelerate understanding and breakthroughs together.

- Admiral Levine, the Assistant Secretary for Health, has met with Long COVID patients, providers, and researchers to hear more about their experiences and how we can harness the federal government's strengths to address their most pressing calls for action. This includes supporting provider education efforts through CDC, working with provider organizations and external groups.
- In November of last year HHS released the Health+ Long COVID Report to better understand the complexities of Long COVID and cultivate creative patient-driven solutions. The Health+ Long COVID Report was commissioned by HHS and produced by an independent third-party design and research firm and includes opportunity areas where clinicians, patient advocacy organizations, public health professionals and leaders in government can improve accessibility to support and services through practical solutions.
- HHS is also working to investigate and promote evidence-based care models. For example, we are investigating how health care systems can utilize telehealth to reach patients in rural communities; how tele-mentoring can connect expert clinicians to primary care practices; and how we advance the development of multispecialty clinics to provide complex care.
- This work would fund institutions across the country that bring together leading researchers and care providers across the full care continuum – including hospitals, health centers, long-term care services and supports, and other providers – and promote the implementation of new evidence into care, especially for disproportionately affected populations.

Q: We are now in the 4th year of the pandemic, why don't we know more about Long COVID already?

- Research is rapidly emerging and every week the scientific and medical community around the world is getting a better understanding of the various Long COVID endotypes and the differing pathophysiology; distinctions necessary to develop diagnostics and therapeutics.
- Long COVID is not one entity, so dissecting it into understandable and manageable components will take time.
- Research is establishing clinical criteria for diagnoses and elucidating possible pathophysiologic mechanisms to inform laboratory and other test development and other diagnostic strategies.
- This foundational research is already providing valuable insights and will inform Long COVID clinical trials, which will help find treatments for those suffering from its effects.
- The U.S. government has a leading role in this Long COVID research through the work it conducts itself, including research in government-led health systems such as the VA and Indian Health Service; by funding private research; and by coordinating efforts across public and private entities.
- The National Research Action Plan lays out the higher level approach to getting this work done.

Q: It seems like HHS is blowing Long COVID out of proportion to scare people-I understand that data from CDC shows that Long COVID is not real.

- [Research suggests between 5% to 30%](#) of those who had COVID-19 struggle with Long COVID symptoms 30 days after their acute infection.
- On December 1, in JAMA Network Open, an academic group of CDC INSPIRE grantees published an interim analysis of overall well-being 3 months after a positive test for SARS-CoV-

2 among an initial adult cohort of 1000 (of the estimated final cohort of 6000) in an multicenter prospective longitudinal cohort study.

- After statistical adjustment, comparing baseline and overall self-reported well-being at 3 months, improvements were greater in the COVID-19 group vs the negative group for social participation, especially among those aged 18 to 34 years and those presenting to ambulatory care for testing. Changes in other domains were not significant.
- The results of the study are preliminary, introduce the INSPIRE study, and demonstrate the importance of a control group. The findings highlight the potential widespread impact of the pandemic on our overall health, including the lesser-tracked emotional, social, and mental aspects, alongside the highly recognized physical effects.
- It is important we recognize that these findings do not negate the existence of Long COVID, or call into question the reality of the patient experience. Infection associated chronic illness is not new. There is substantial ongoing research on infection-associated chronic conditions and other diseases that may have infectious origins, including dysautonomia and ME/CFS. It is important to build on this research to achieve a deeper understanding of Long COVID and guide us to effective responses that protect the nation's long-term health.

Q. I continue to read in the news that people with Long COVID are being denied Social Security Disability Insurance. What is HHS doing to ensure SSA is working to provide economic relief for those who have become disabled or unemployed due to Long COVID?

- I defer to my colleagues at the Social Security Administration to provide more information on Social Security Disability Insurance (SSDI). However, we are working with them closely to move forward.
- I do want to share that separate from SSDI, HHS worked with the Department of Justice to publish guidance on Long COVID as a disability. Long COVID may be considered a disability under civil rights laws, which can protect people from discrimination.
 - o Titles II (state and local government) and III (public accommodations) of the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973 (Section 504), and Section 1557 of the Patient Protection and Affordable Care Act (Section 1557). Each of these federal laws protects people with disabilities from discrimination.

COVID – Mandates

TALKING POINTS:

- Time and time again, we have seen that the vaccine is both incredibly safe and effective against severe disease and death from COVID-19.
- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.
- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - o 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.

If asked about foreign national mandate:

- Evidence continues to show that vaccination does offer substantial protection against severe infection and hospitalization, and vaccines do offer some protection against infection.
- Having fully vaccinated travelers reduces the impact on the US public health and health care system.
- That said, the Administration is engaged in ongoing discussions about this policy.

QUESTIONS:

Q: Why is there still a Vaccine Mandate in place for health care workers when the PHE is ending May 11th?

- One way to prevent health care workforce shortages is to ensure they are healthy.
- The staff vaccination requirement for all Medicare and Medicaid certified providers has been enforced in all states since February 20, 2022. To date, most providers surveyed by states have been found to be in substantial compliance with this requirement.
- The requirements in the Omnibus COVID-19 Health Care Staff Vaccination interim final rule with comment will expire on November 5, 2024 if CMS does not take additional action.
- That said, the Administration is engaged in ongoing discussions about this policy.

Q: Why is there still a Vaccine Mandate for Head Start when there is a shortage of child care access for working families?

- One way to prevent health care workforce shortages is to ensure they are healthy.

- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.
- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.
- That said, the Administration is engaged in ongoing discussions about this policy.

Q: Why did CDC close schools?

- This Administration prioritized opening schools for the critical role they play in not only educations, but support for children through school meal programs and social, physical, behavioral, and mental health services.
- Three weeks after this Administration took office, CDC released guidance that served as a roadmap for how schools could open safely.
 - Prior to the release of this guidance only 46 percent of schools were offering full-time instruction. Just a few short months after, over 60 percent of schools offered full-time instruction and by the fall of that year, 95 percent of schools offered full-time instruction.

Q: Why did CDC send its school guidance to the teacher's union?

- When developing guidance and recommendations, CDC often engages with organizations and groups that are impacted. The agency does so to ensure recommendations are comprehensive, consider stakeholder needs and concerns, and are feasible to implement.
- These informative interactions result in beneficial feedback for final revisions to promote clarity, completeness, and usability.
- For the development of the school guidance, CDC had close engagement with the U.S. Department of Education and sought input from 50+ different organizations and stakeholders—including teachers, superintendents and parents to discuss experiences, challenges, and lessons learned in implementing prevention strategies for infectious diseases in K-12 schools.

Q: What is CDC's role in setting vaccine mandates?

- CDC collects data on the effectiveness of vaccines and the uptake of those vaccines in population groups (general public, healthcare workers, children, etc.)
- CDC also provides information to the general public and policymakers about the state of infectious disease outbreaks (influenza, COVID-19, mpox)
- CDC makes recommendations about who should be vaccinated and when based on the science

- CDC makes this information available to policymakers who are ultimately responsible for making decisions about vaccine requirements. Policymakers can use this information to make decisions about the populations they are responsible for protecting.

Q: Now that we know the vaccines do not prevent transmission, will you go on the record to acknowledge that there is no scientific rationale justifying a vaccine mandate for COVID-19?

- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.
- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.
- That said, the Administration is engaged in ongoing discussions about these policies.

COVID - Misinformation

TALKING POINTS:

- Bridging the health equity divide has been a critical component of the COVID-19 pandemic response. Americans in rural, urban, and tribal areas must have access to public health interventions and we are actively finding and closing these gaps.
- HHS is working to reach people where they are, but disinformation and misinformation often reaches them faster.
- We needed trusted messengers to help. Americans don't always want to hear from a government official, sometimes they want to hear from somebody in their local pharmacy or their local pediatrician.
- HHS works with our Pharmacy Partners and our We Can Do This campaign to use trusted community messengers to answer questions and provide accessible information about vaccines.
- It takes all of us to tackle disinformation and misinformation.

Questions:

Q: What is the impact of misinformation regarding vaccines?

- Vaccination coverage has dropped a total of 2 percentage points since the start of the pandemic for kindergartners. In real terms, this **means 250,000 kindergartners not getting their vaccinations.**
- To stop misinformation from eroding public trust in vaccines, CDC will continue its work with local partners and trusted messengers to improve [confidence in vaccines](#) among groups placed at higher risk, including racial and ethnic minorities and with parents of very young infants and expectant parents.

Q: While serving in this Administration, have you, or any of your staff, ever asked a technology company to take down an American's social media post regarding the pandemic response?

- Thank you for the question. Because there is pending litigation, I'm not going to get into any specifics on that today. But what I will say is that COVID-19 misinformation spread online is a serious issue that has real public health impacts.

Q: What is HHS doing to combat misinformation?

- HHS has undertaken a campaign which has activated partnerships, digital outreach, influencers, and paid media to reach Americans where they are, with a focus on outreach around new COVID-19 vaccine authorizations.
- The campaign has hosted over 400 COVID-19 vaccine educational booths and vaccine pop-up clinics in more than 90 cities. HHS has also launched the COVID-19 community corps, a network of nearly 20,000 community leaders and volunteers who serve as trusted local voices.

COVID – Origins

COVID – Origins (China)

TALKING POINTS:

- For more than two years, China has blocked international investigators and members of the global public health community from accessing information related to COVID-19 origins. This is unacceptable – and we must not let this prevent us from getting answers.
- The fact is that the Chinese government hasn't been transparent enough. For us to be able to get to the bottom of this, we need critical information about the origins of this pandemic that exists in the People's Republic of China.
- Yet from the beginning, government officials in China have worked to prevent international investigators and members of the global public health community from accessing it.

QUESTIONS:

Q: Will this Administration hold China accountable for obstructing efforts to investigate covid origins?

- The fact is that the Chinese government hasn't been transparent enough. This is unacceptable – and we must not let this prevent us from getting answers.
- We will continue to work with partners around the world to press China to fully share information and to cooperate with international investigations.
- Getting to the bottom of the origins of COVID-19 remains a priority for this Administration.

Q: Do you support calls to sanction China until it fully complies with international investigations?

- I'm not here today to opine on foreign policy. But what I will say is that the Chinese government hasn't been transparent enough on this issue – and that is unacceptable.

COVID – Origins (IC Assessments)

TALKING POINTS:

- President Biden has directed, repeatedly, every element of our intelligence community to put the effort and resources behind getting to the bottom of the origins of COVID-19.
- There are a variety of views on this issue in the intelligence community. Some elements have reached conclusions with varying levels of confidence on one side, some on the other, and others have said they don't have enough information.
- Valuable, bipartisan work remains to be done to address the Chinese government's lack of transparency and ensure investigators can access this critical information about the origin of COVID-19, so we can better understand how to prevent future pandemics.

QUESTIONS:

Q: Do you think that the “lab leak” theory is misinformation or a conspiracy theory?

- I think it's important to be precise here. On the one hand, some elements of the intelligence community have concluded, with varying degrees of confidence, that the coronavirus may have escaped from a lab. However, I am not aware of any evidence that the coronavirus was intentionally released as a biological weapon.
- There is no doubt that this is an important question. That's why this Administration has, from the beginning, prioritized efforts to get to the bottom of the origins of COVID-19.

Q: Both the Energy Department and the FBI have now concluded that the coronavirus likely originated from a lab leak. What is HHS's current assessment?

- We don't currently know the precise origins of the pandemic.
- The scientific evidence to date suggests that the virus is the result of normal viral evolution and not the result of genetic modification in a lab.
- The question that remains is if researchers working with infected bats or samples accidentally became infected and unintentionally spread it to others.
- There is no hard evidence to indicate that this happened, but certainly, it's something we want to know. Importantly, that will require cooperation from China and other countries to get to that information.

Q: Did Dr. Fauci tell the truth about Covid origins?

- Political attacks on public health officials like Dr. Fauci who have spent their careers saving lives are completely counterproductive.
- Dr. Fauci has said he agrees with the President that we need to get to the bottom of how COVID originated.
- I'll let Dr. Fauci speak for himself. We have been grateful for his wisdom and advice during the COVID response, and we have all been very clear that we will use every tool to figure out what happened here.

COVID – Origins (EcoHealth/Gain of Function Research)

TALKING POINTS:

- Research on infectious diseases helps develop vaccines and treatments and needs to be done safely, securely, and transparently -- here and abroad.
- HHS takes its responsibility to be a good steward of taxpayers' investment in biomedical research seriously.
- To that end, last year HHS tasked the National Science Advisory Board for Biosecurity (NSABB) to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.

- The NSABB issued its final report and recommendations earlier this month. HHS, and our interagency partners, will consider this report as part of a broader government-wide review process, which aims to effectively balance science and security, while safely enabling critical lifesaving research.

QUESTIONS:

Q: Did the NIH through its EcoHealth grant fund gain-of-function research in the Wuhan Institute of Virology (WIV) that resulted in COVID-19?

- No. NIH has never approved any research that would make a coronavirus more dangerous to humans.
- The research we supported in China, where coronaviruses are prevalent, sought to understand the behavior of coronaviruses circulating in bats that have the potential to cause widespread disease.
- The body of science reported—including the bat coronavirus sequences published in the scientific literature—showed that the viruses studied at WIV under the NIH grant were evolutionarily quite distant from SARS-CoV-2 and could not have been the source of the COVID-19 pandemic.
- And importantly, because of similar research to understand coronaviruses, we were able to move swiftly to develop vaccines against SARS-CoV-2 and save lives.

Q: Why does HHS support research in China at all?

- HHS supports research to better understand the characteristics of animal viruses that have the potential to spill over to humans and cause widespread disease.
- We must collaborate with researchers in other countries where these sorts of viruses are prevalent because once a virus spreads to humans, it is not contained by geographical boundaries.
- Infectious outbreaks have happened throughout history. Let's not forget the SARS epidemic in 2003 that was traced to civets as an intermediate host or the H1N1 flu pandemic in 2009 that originated from pigs.
- The body of research on pathogens and infectious diseases is what has made it possible for the U.S. government to move so quickly to get a COVID-19 vaccine in an unprecedented timeframe of just 11 months. Countless lives have been saved as a result.

Q: What is this Administration doing to ensure taxpayers are not funding risky biomedical research that could lead to another public health crisis?

- In February 2022, NIH tasked the National Science Advisory Board for Biosecurity (NSABB) to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.
- In March 2023, the NSABB issued its final report containing its findings and recommendations.

- These findings and recommendations will inform ongoing USG policy deliberations.

Q: The HHS OIG recently found that NIH did not effectively monitor or address EcoHealth's compliance with grant requirements, when it was conducting risky research at the WIV. Dr. Larry Gostin, who has advised this White House on the pandemic response, called the OIG report a "damning indictment of NIH." Do you agree?

- We respect the OIG's findings and have taken action to address their recommendations.
- HHS takes its responsibility to be a good steward of taxpayers' investment in biomedical research seriously. We are committed to conducting oversight of the research we fund to ensure safety, security, and responsible conduct.
- That's why we charged the NSABB to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.
- Additionally, recipients of NIH awards are accountable for ensuring the stewardship of federal funds and must comply with all applicable federal statutes, regulations, policies, and institutional requirements.

COVID - OTC Tests

TALKING POINTS - MEDICARE:

- CMS prioritizes supporting beneficiary access to the care they need and after the end of the public health emergency (PHE).
- Medicare beneficiaries can continue to access medically necessary COVID-19 polymerase chain reaction (PCR) tests and antigen tests performed by a laboratory at no cost to them when the test is ordered by a physician or non-physician practitioner and some Medicare Advantage plans may continue to provide coverage for these tests as a supplemental benefit.
- By law, Medicare does not generally cover over-the-counter (OTC) services and tests. Current access to free OTC COVID-19 tests will conclude at the end of the PHE. When the demonstration was implemented, it was announced that the demonstration would end at the end of the PHE.

TALKING POINTS – OTHER PLANS:

- The requirement to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end at the end of the PHE - coverage may continue if plans choose to continue to include it, which we are encouraging them to do.

QUESTIONS:

Q: Will CMS be extending the Medicare OTC demonstration?

- When CMS implemented this demonstration, we stated that CMS would pay claims for over-the-counter COVID-19 tests starting on or after April 4, 2022, through the last day of the COVID-19 public health emergency, which the President announced would be May 11, 2023.
- After the end of the COVID-19 PHE, Medicare beneficiaries can continue to access medically necessary COVID-19 polymerase chain reaction (PCR) tests and antigen tests performed by a laboratory at no cost to them when the test is ordered by a physician or non-physician practitioner.
- Some Medicare Advantage plans may cover and pay for at-home over-the-counter COVID-19 tests as a supplemental benefit in addition to Medicare Part A and B benefits, so consumers enrolled in Medicare Advantage plans should check with their plans to see if they offer this benefit separate from coverage for all Part B enrollees under the demonstration.

Q: What about Medicaid coverage?

- Under the American Rescue Plan Act of 2021, State Medicaid programs are required to cover FDA-authorized home diagnostic and screening tests for COVID-19 for most Medicaid beneficiaries without cost-sharing, until the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE.

- Because Medicaid coverage parameters may vary by state, people dually eligible for Medicare and Medicaid and who are eligible for full Medicaid benefits should contact their state Medicaid agency for information regarding the specifics of Medicaid coverage for at-home COVID-19 tests.

Q: What about private insurance coverage?

- The requirement for group health plans and health insurance issuers offering group or individual health insurance coverage to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end at the end of the PHE. However, coverage may continue if plans choose to continue to include it. We are encouraging private insurers to continue to provide such coverage going forward.

COVID - Vaccine Safety

TALKING POINTS:

- Time and time again, we have seen that the COVID-19 vaccines are both incredibly safe and effective against severe disease and death from COVID-19.
- Vaccination remains the safest and most dependable strategy to build immunity. Most adverse events following vaccination are mild and resolve quickly, such as pain at the injection site and fever. Serious adverse events are rare.
- That said, COVID-19 vaccine safety remains a top priority for HHS, and reports of health problems are taken seriously. CDC, FDA and its partners use several complementary vaccine safety systems to monitor for adverse events.
- We are dedicated to transparency and report findings from safety monitoring publicly, as part of an open and transparent process, to CDC's Advisory Committee on Immunization Practices (ACIP), to FDA's Vaccines and Related Biological Products Advisory Committee, and to update the information for health care providers, caregivers and recipients, as appropriate

QUESTIONS:

Q: HHS agencies have repeatedly told the American people that the vaccines are safe. But CDC's data monitoring system has detected evidence of a link between the vaccines and strokes. Can you acknowledge that your Department's own data show that the vaccines pose risk of serious adverse effects for at least some Americans?

- For decades, our scientific agencies have used safety monitoring systems to look for even the slightest clue of a potential safety issue in our medicines, including vaccines. In most cases, signals detected by these systems do not add up to safety risks, but we investigate all these signals to ensure trust in our medicines.
- As part of CDC's routine surveillance, CDC detected a signal for potential stroke in people ages 65 and older who received the Pfizer-BioNTech bivalent vaccine. In response, CDC and FDA examined several large databases to see if these systems had detected a similar signal. To date, our analyses of all of these large databases do not show an association or increased risk of stroke from the Pfizer-BioNTech bivalent vaccine.
- We continue to conclude that the bivalent vaccines are safe and effective and provide the best protection against COVID-19, and we continue to recommend that Americans of all ages get their updated COVID-19 vaccine right away.

Q: Americans have been pressed to take a series of vaccine doses in less than two years. And now, this Administration is indicating that the public—including children—should expect a sustained pressure campaign to take a shot each year. If the vaccine is so effective, how come Americans are being asked to take them constantly?

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- Evidence continues to show that the COVID-19 vaccine is remarkably safe and effective at preventing severe disease and death.
- Vaccination also does reduce the impact on the US public health and health care system.
- And making sure you are up-to-date on booster shots is an important part of protecting yourself from getting seriously ill or dying from COVID-19.

Cybersecurity

TALKING POINTS:

- Cyber incidents pose risks to patient data, intellectual property, scientific research, medical manufacturing, and ultimately the ability of health care organizations to safely serve their patients. We must take all steps necessary to prevent them.
- Just this month, the Department released a new roadmap to help health care organizations improve their cybersecurity amid new emerging threats and increased attacks on systems. We hope to leverage and further incentivize our private sector partners to strengthen critical infrastructure and safety writ large.
- In February, we announced that our Office for Civil Rights is realigning to address this spike in health data breaches. Across the board, we are working to remain nimble internally to respond to bad actors throughout the sector.
- In December, the FDA received new authorities through the omnibus requiring medical device manufacturers to implement cybersecurity protections on devices before they hit the market.

QUESTIONS:

Q: How concerned are you about cyber attacks in the healthcare sector? How is HHS helping when cyber incidents occur?

- Patient safety is our #1 priority, and safety is compromised by these cyber incidents. A significant consequence of US hospital-directed cyberattacks are the extended disruptions that are caused by long outages and disrupt our healthcare system's ability to provide care (e.g., strain on acute care capacity and ability, causing loss of appointments, loss of services, and delayed medical procedures).
- These attacks also cost hospitals financially – one recent attack on a major health system cost them at least \$150M; the \$150 million financial impact includes lost revenues due to business disruption and extra costs to fix the IT issues. These attacks threaten the solvency of health care facilities, and thus can potentially reduce access and availability of care.
- When incidents occur, we work with our government partners, such as CISA and FBI to investigate; HHS investigations center around the impact to patient safety.
- We stand ready to protect patients when incidents occur through our incident response capabilities within ASPR.

Q: What is HHS doing to support the healthcare and public health sector on cybersecurity?

- The best defense is a good offense – we encourage providers to be proactive and take the necessary steps to prevent incidents by securing their networks and data.
- HHS partners with our private sector and interagency partners to release cybersecurity guidance and best practices for health care organizations to implement; we encourage healthcare organizations to remain vigilant.

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- Additionally, any data breach with patient data is reported to the Office for Civil Rights for further investigation – and follow on action (including penalties) as necessary.
- Finally, the FDA plays a big role through the regulation of medical devices – through the FY 2023 omnibus the FDA will now have the authority to require cybersecurity protections on medical devices BEFORE they enter the market.

DEA Regulations

TALKING POINTS (TELEMEDICINE)

- DEA released new **proposed** regulations related to the practice of telemedicine.
- HHS has worked with our DOJ partners on these proposed rules to make sure that people can continue to access telemedicine for critical controlled medications, including buprenorphine treatment for Opioid use disorder.
- Finalizing regulations to extend these flexibilities is critical to ensure minimal disruption and a smooth unwind of the public health emergency
- At HHS, our priority is ensuring access to care for critical services. Pre-pandemic law would be a dramatic rollback of what we learned to be critical access to care that can often be lifesaving.
- We look forward to stakeholder feedback and working with our DOJ colleagues to take that into account and finalize a rule.

TALKING POINTS (X-WAIVER):

- The Omnibus included provisions that better integrate opioid use disorder care into primary care and expand access in rural areas, which the DEA and SAMHSA are implementing. This includes:
 - Removal of the X-waiver and removal of buprenorphine patient caps
 - Implementation of one-time training and education requirements for prescribers wishing to prescribe medication assisted treatment (MAT)
- We are currently working across the Administration to implement these new provisions related to substance use disorders and to produce informative materials for those who are impacted by the new provisions.
- We are supportive of efforts to reduce barriers to treatment because ultimately, this is about saving lives.

QUESTIONS – TELEMEDICINE:

Q: What happens on May 11 when the PHE expires?

- Our work with DEA is about making permanent changes to the regulations that currently apply from pre-pandemic days.
- Once the PHE expires on May 11, and state-level PHE's expire, we know we should not go back to operating the way we did pre-pandemic. We have learned how lifesaving telemedicine is and want to permanently put into place what we know is critical to improving access to healthcare.

- This is why it's critical to take these steps as soon as possible and permanently put in place new, more expansive flexibilities (*as compared to pre-pandemic*) before the PHE expires on May 11.
- We know this is a complicated issue, and we want to make sure we get it right, which is why robust comment is so important during this comment period.

Q: You are encouraging the public to comment but didn't the announcement come out after 7pm on a Friday evening?

- We are in a time limited situation, and we want to get it right. We announced this as soon as we got it cleared because every day counts.
- We need to hear from the public on this rule so we can get this right.
- If these updated, more flexible regulations do not go into place as soon as the PHE expires, we will be left with the older pre-pandemic policies governing telehealth initiation of controlled medications, which were far more restrictive – and everything we learned about improving access to care will be lost.

Q. You claim to support access to buprenorphine, yet the DEA's proposed rules would roll back some flexibilities that have been in place since the pandemic started. Do you support this proposal?

- We have heard lots of differing perspectives on the proposed rules and appreciate the stakeholder engagement.
- We are in a time limited situation, and we want to get this right. Going back to Pre-pandemic rules would dramatically rollback access.

QUESTIONS – X-WAIVER:

Q: How will the removal of the X-Waiver improve access for patients to medications for opioid use disorder?

- The removal of the requirement for practitioners to obtain a waiver will make it easier for qualified practitioners to prescribe medications for opioid use disorder, builds on the Department of Health and Human Services' Overdose Prevention Strategy, and delivers on the call to action in President Biden's Unity Agenda to expand access to evidence-based prevention, treatment, and recovery services.

Q: Isn't removing the training requirement in the X-waiver a concern? Isn't that how we got in this epidemic in the first place?

- The alarming increase in overdose deaths underscores the need for more accessible treatment services, and studies have shown that medication-based treatment promotes long-term recovery from opioid use disorder.

- The spike we've seen in opioid involved deaths during the COVID-19 pandemic requires us to do all we can to make treatment more accessible.
- At the same time, we know that education on substance use disorders is important as practitioners diagnose and treat these conditions. HHS is working with professional societies to ensure that appropriate education is provided to their members so that the ongoing education and training needs of healthcare professionals are met, regardless of the existence of the X-waiver itself.

Q: Is there abuse potential for buprenorphine-naloxone? In other words, could someone use it to achieve a "high?"

- Though we are aware of some diversion of buprenorphine, these instances are rare and when they do happen, it is typically because people are seeking treatment, not attempting to get "high." This is all the more reason for us to take steps to expand access to buprenorphine.

Q: Will HHS maintain the regulatory flexibilities for medication-assisted treatment for the remainder of the Public Health Emergency while it considers making these policies permanent?

- HHS, through SAMHSA, has indicated it will work to revise the relevant regulations to make permanent some flexibilities for opioid treatment programs.

Debt Ceiling

TALKING POINTS:

- The Administration's position has been clear – we must avoid dangerous brinksmanship and agree to a clean raise of the debt ceiling.
- The President's budget will build on the last few years' progress, invest in America, and strengthen our fiscal outlook.
- The Administration welcomes a conversation with congressional Republicans about their competing vision, and that's why we've urged them to put forward their own budget, which is a necessary step to having that conversation.
- The President has been clear about some things he won't agree to, including cutting Medicare benefits or taking away people's health care.

QUESTIONS:

Q: Will this Administration accept work requirements for Medicaid beneficiaries?

- Let's be clear: Medicaid is a lifeline to tens of millions of hardworking American families across the country.
- My goal is to use all available tools to protect and strengthen the Medicaid program, making it easier, not harder for people to get and keep health insurance that helps them to become healthy, not pulls the rug out from under them.
- *If pushed:*
We would not approve any demonstration that would result in significant numbers of Medicaid beneficiaries losing coverage.

Q: Will this Administration negotiate on Medicaid

- Medicaid is a lifeline to tens of millions of hardworking American Families- including one in every two children. The President's budget would strengthen our fiscal outlook and cut the deficit by investing in America, not paying for it on the backs of hardworking families.

Q: What will cuts to non-defense discretionary spending mean for HHS?

- This is the funding for medical research, public health programs at the CDC and other HHS agencies, grants for substance use and mental health treatment, and various other programs.
- Cuts will have a significant impact on the Department's work and ability to provide services, assist people in need, and make necessary investments.

(CMS) Drug Pricing Reform

TALKING POINTS:

- The Budget builds on the transformative prescription drug provisions included in the Inflation Reduction Act to further lower the cost of prescription drugs for Americans:
 - Strengthen Medicare's newly established drug pricing negotiation power by allowing Medicare to negotiate prices for more drugs and bringing drugs into negotiation sooner after they launch, saving \$160 billion over 10 years.
 - Extend the requirement that drug companies pay rebates when they increase prices faster than inflation to commercial health insurance, not just Medicare.
 - Limit cost-sharing for insulin to \$35 per month for all consumers covered by commercial plans, not just Medicare beneficiaries.
- The Budget further reduces out-of-pocket costs for people with Medicare by capping copayments for Part D generic drugs at maximum of \$2 per prescription per month.
- The Budget addresses the high cost of drugs in Medicaid and CHIP by establishing a process for CMS to lead states in negotiating supplemental rebates to pool purchasing power for lower prices.

QUESTIONS:

Q: How many drugs are you including in your proposal to expand drug price negotiation to achieve \$160 billion in savings over 10 years? Is that realistic?

- First, let me say that I am proud to be part of the Administration that passed one of the most significant health reform bills since the creation of Medicare. The Inflation Reduction Act makes Medicare stronger for current and future enrollees. It makes health care more accessible, equitable, and affordable by lowering what Medicare spends for prescription drugs and limiting increases in prices, reducing the deficit by \$159 billion.
- Our Budget builds on the Inflation Reduction Act by increasing the number of drugs subject to negotiation, eventually negotiating on up to 40 drugs, and making drugs eligible for negotiation sooner after their launch. Expanding the Drug Price Negotiation Program will lower costs for people with Medicare and the program, for an additional \$160 billion in savings over 10 years.
- We will take the increased savings and put them directly into the Medicare trust fund, helping to extend Medicare's solvency. As always, we will continue to work with Congress on the specifics of these proposals.

Q: Won't drug price negotiation raise the prices of new drugs, so doesn't the Budget contribute to higher prices for new drugs?

- Manufacturers use many factors when considering their launch prices and will continue to price their drugs at the price they believe the market will bear. We are proposing to

make drugs eligible for negotiation sooner after they launch, permitting time on the market for five years. Under current law and under our proposal, any drug or biological product selected for negotiation will have been on the market for some time. CBO didn't estimate that the new Drug Price Negotiation program would have a significant impact on launch prices, and we do not believe our proposal will contribute to significantly higher launch prices.

Q: Aren't drug price negotiations really price controls that will hinder drug development?

- We support innovation and believe it is vitally important that people with Medicare have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.
- By reducing prices for high-cost drugs, our expansion of Medicare drug price negotiation will not only save money for the federal government, but it will also cut Medicare beneficiary out-of-pocket costs by billions of dollars.

Q: Won't drug price negotiation crush innovation and kill hundreds of new cures? Studies have found that the IRA's negotiation provision would kill up to 342 cures.*

- We support innovation and believe it is vitally important that people with Medicare have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.
- Medicare's drug price negotiation program will make drugs more affordable for people with Medicare. Remember, only drugs that have been approved or licensed by the FDA for a number of years are eligible for negotiation.
 - *[The number 342 has been used by some to argue that drug price negotiation will lead to fewer new drugs and refers to a [University of Chicago study](#) based on provisions in H.R.3, Lower Drug Costs Now, that finds fewer drug approvals ranging from 167 to 342.]

Q: Regarding making the Medicaid Drug Rebate Program (MDRP) optional for territories, why is this needed? Doesn't joining the MDRP result in more savings for territories?

- Territories' Medicaid programs operate under a unique set of conditions that differ from states. While participating in the Medicaid Drug Rebate Program leads to savings, these savings could be more than offset by the increase in costs from the additional drugs that territories would need to cover under the MDRP. The five territories are very different and will not experience the same economic impact by joining as states. This proposal effectively gives territories the option to make the best choice for their Medicaid program resources and needs. Excluding sales of drugs to territories from the average

manufacturer price and best price calculations mitigates possible increased drug prices in territories.

Drug Pricing Executive Order

TALKING POINTS:

- HHS was tasked by the President to select models to test to bring down prescription drug costs.
- I selected three models identified by the Innovation Center that we believe will lower prescription drug costs and improve access for people with Medicare and Medicaid, including, in Medicare, access to certain generic drugs for no more than \$2.
- To help identify model options, we solicited input from a variety of sources including beneficiary advocates, health care providers, and prescription drug manufacturers, and we look forward to additional input as these models are further developed.

If pressed about mandatory models

- Two of the models are voluntary. Only one model, the Accelerating Clinical Evidence Model, would be mandatory for physicians billing Medicare for Part B drugs, and this model would only be implemented after a full notice and comment rulemaking cycle.

QUESTIONS:

Q: The FDA's Accelerated Approval Program has brought groundbreaking therapies to patients' years before these products would have otherwise reached the market. The Accelerating Clinical Evidence Model recently announced by CMS risks undermining this progress. Will you consider canceling or delaying the Model?

- The Accelerating Clinical Evidence Model will not change the way CMS covers new drugs, and it does not change the FDA accelerated approval process. The model is intended to test whether changes to Medicare payment might encourage evidence development via timely completion of confirmatory trials. We are still exploring the specific approaches to payment adjustments, and we look forward to close consultation with the FDA and hearing from stakeholders on how the Model should be developed.

Q: The IRA did not address the high cost of drug launch prices; how will these models tackle that challenge?

- High launch prices are among many factors that impact affordability for beneficiaries. Each of the selected models addresses the objectives of the President's executive order and meets the selection criteria of increasing affordability, accessibility, and feasibility of implementation.

Q: The IRA did not address the perverse incentives created by PBM rebates, how will these models tackle that challenge?

- The executive order directed the Innovation Center to explore a variety of factors addressing prescription drug costs. The effect of rebates on prescription drug costs is one among many factors that contribute to high and rising drug costs for beneficiaries. The selected models address the objectives of the President's executive order and meet the selection criteria of increasing affordability, accessibility, and feasibility of implementation.

Q: Part D plans already offer low-cost generics; what does the High-Value Drug List model intend to accomplish?

- This model would encourage plans to expand their current low copay drug offerings and provide beneficiaries access to a standardized list of generics with copays of no more than \$2 across participating plans. The simplicity and consistency of the drug list could provide beneficiaries with greater predictability and transparency with their drug costs and enable them to more easily access low-cost generics.

Q: How does the Medicaid Cell & Gene Therapy Access Model differ from what states can already do?

- State Medicaid agencies may negotiate with manufacturers for supplemental rebates on prescription drugs and may form multi-state purchasing pools for purposes of these negotiations. However, states' abilities vary, and the resources necessary to negotiate outcomes-based supplemental rebate agreements are far greater than other types of rebate agreements. This model will help to address that challenge for states and encourage adoption of outcomes-based agreements on a broader scale for certain cell and gene therapies, like for sickle cell disease and cancer.

Early Childhood Education

(Dollars in Millions)

Discretionary Table	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Child Care and Development Block Grant (Discretionary)	8,021	9,000	+979
Head Start (Discretionary)	11,997	13,112	+1,115
Preschool Development Grants (Discretionary)	315	360	+45
Total, Discretionary	20,333	22,472	+2,139

Mandatory Table	FY 2023 Enacted	FY 2024		10 Years
		Budget	+/- FY 2023 Enacted	
Budget Authority - Child Care Entitlement	3,550	3,550	-	35,500
Total, Child Care Entitlement	3,550	3,550	-	35,500
Budget Authority - Affordable Child Care for American Families	-	9,900	-	400,000
Budget Authority - Universal Preschool	-	5,000	-	200,000
Total, Early Care and Education	-	14,900	-	600,000

Talking Points:

- Approximately 1.5 million children receive child care assistance from the Child Care and Development Fund. The new mandatory investment in high-quality child care would expand coverage options to more than 16 million children in low- and middle-income families.
- Under our budget, lowest income families would pay nothing and middle-income families would pay no more than \$10 per day per child for child care.
- The budget would allow all four million 4-year-old children in the nation to have access to high-quality, universal, free preschool, while also charting a path to expand free preschool to 3-year-olds. Currently, less than half of all 4-year-old children and just 17 percent of all 3-year-old children attend publicly funded preschool.
- The budget provides \$22.5 billion in discretionary Child Care, Head Start, and Preschool Development Grants, an increase of \$2.1 billion over FY 2023 Enacted. The budget also

continues to help over 2.5 million children have access to early learning programs through our existing Child Care, Head Start, and Preschool Development Grants programs.

QUESTIONS:

Q: How will Early Childhood Education help low and middle-income families access high quality and affordable child care?

- The President's Budget includes \$600 billion over 10 years to expand access to affordable, high-quality child care and free, high-quality preschool, helping children learn, giving families support, and growing the economy.
- Low- and middle-income families will pay the lowest co-pays – with a goal of ensuring that the lowest income families pay nothing and that most families pay no more than \$10 per day per child.
- A median-income family with young children saves about \$400 per month while accessing higher quality care.

Q: What is in the Early Childhood Education - Affordable Child Care for American Families proposal?

- The FY 2024 Affordable Child Care for American Families proposal costs \$400 billion over 10 years and provides higher federal matching funds for child care providers serving low- and middle-income families and allows those families to pay the lowest co-pays, with a goal of ensuring that the lowest income families pay nothing and that most families pay no more than \$10 per day per child.

Q: What is in the Early Childhood Education - Universal Preschool proposal?

- The Universal Preschool proposal expands high-quality preschool to approximately four million 4-year-old children, with states later expanding to 3-year-old children once preschool is expanded to all 4-year-old children.
- The Universal Preschool proposal includes funding to provide access to preschool to children in underserved communities in states that do not choose to participate in the new preschool program, so that families in every state have access to high-quality preschool.

Equity

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
ACF	71,470	94,374	+22,904
ACL	2,105	2,551	+445
AHRQ	4	12	+9
CDC	378	674	+297
FDA ¹	19	19	--
HRSA	7,589	8,634	+1,045
IHS ²	7,105	9,650	+2,545
NIH	95	95	--
CMS	83	82	-1
OASH	75	86	+11
OCR	40	78	+38
Total Program Level	88,963	116,256	26,293

1/The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year

2/ Reflects total IHS funding with the exclusion of third-party collections. The FY 2024 budget proposes mandatory funding for Contract Support Costs and Section 105(l) Leases. Funding for these activities is discretionary in FY 2023.

TALKING POINTS:

- Equity remains a core value and consideration in the Department's budget and program implementation. We strive to reduce systemic health and social disparities for individuals and families, and combat inequities in access to care.
- Some highlights in our budget – we included \$8.6 billion to care for low-income and underserved populations through Health Centers, health care workforce expansion, rural health, HIV/AIDS, and maternal and child health services. The budget takes long-overdue action to improve the health status of over 2.8 million American Indians and Alaska Natives served by the Indian Health Service (IHS) with historic funding levels. ACF also will provide \$50 million in new grants to address racial inequities in child welfare, and reduce overrepresentation of racial / ethnic minority children and families.
- The budget invests over \$2.6 billion to provide critical services and supports to older adults and people with disabilities, with a particular emphasis on serving the most vulnerable in greatest social and economic need (through Administration for Community Living (ACL) programs).

QUESTIONS:

Q: In what ways has CMS focused on equity in the budget?

There are many proposals in the budget that have a positive equity impact. Key examples include:

- **Medicaid:** The budget eliminates barriers to Pre-exposure Prophylaxis (PrEP) for HIV/AIDS, increases access for Medicaid beneficiaries seeking HIV prevention tools, including populations most vulnerable to HIV/AIDS. The budget also requires postpartum coverage for 12 months under Medicaid, including for populations with the highest maternal and infant mortality rates. It also supports dually-eligible individuals by reducing administrative barriers for enrollment and simplifying the process for renewing eligibility in the Medicare Savings Program.
- **Medicare:** The budget also improves data on health disparities by requiring post-acute care providers to report standardized data on social determinants of health, and allows the collection of demographic and social determinants data through Medicare quality reporting programs. The budget adds Medicare coverage of services furnished by community health workers to improve access for underserved beneficiaries
- **Private Insurance:** The budget would fulfill the intention of the ACA by providing a premium-free plan to individuals below 138 percent of the poverty level in states that have not expanded Medicaid, potentially decreasing the number of uninsured individuals by over 2 million. This proposal is a \$200 billion allowance government-wide.
- **Program Management:** The budget includes \$25 million in discretionary budget authority for an initiative to develop tools for States and tribes to address disparities, expand innovative approaches for integrating equity into CMS's programs and policies, build analytic systems to integrate data on underserved populations, and develop dashboards and other products to support interventions to reduce disparities.

Q: The CDC declared racism a public health emergency in 2021. What is the Department doing to improve minority health and reduce health disparities?

- The Health Resources and Services Administration improves health outcomes and achieves health equity through access to quality services, a skilled health workforce, and innovative, high-value programs. HRSA is the primary federal agency that improves access to healthcare services for people who live in underserved and rural communities across the country.
- The National Institute on Minority Health and Health Disparities will continue to expand investments in research on health disparities, fostering collaborations and partnerships to address long-standing inequities.
- NIH will continue to support the UNITE initiative, an NIH-wide effort committed to ending racial inequities across biomedical research.
- Congress provided increased funding for disparities research at NIMHD in FY23. This budget will continue to fund these efforts.

Fentanyl/Overdose Prevention

TALKING POINTS:

- Drug overdoses are a leading cause of death for Americans - more than 107,000 Americans died from a drug overdose in the 12-month period ending in August 2022.
- The overdose crisis has evolved beyond the use of prescription opioids to include increased use of illicit opioids, such as fentanyl, and in combination with other drugs like cocaine and methamphetamine. We are focused on using evidence-based strategies to save lives like using naloxone and expanding access to medications to treat opioid use disorder.
- The budget addresses the **overdose epidemic** by investing \$10.9 billion, including \$9.8 billion in discretionary funding, in programs addressing opioids and overdose-related activities across HHS. These programs support the goals of the HHS Overdose Prevention Strategy.

If pressed for specific examples:

- \$6.2 billion for SAMHSA programs, including the Substance Use Block Grant and the State Opioid Response Grant, which provide grants to states to address the overdose crisis.
- \$736 million for the CDC to expand overdose prevention programs.
- \$79 million for the FDA to implement the Overdose Prevention Framework, which supports programs to promote appropriate prescribing, expand access to naloxone, ensure access to evidence-based treatments, and increase surveillance, enforcement, and indictment of illegal products at international mail facilities.
- \$50 million for a new Community Harm Reduction and Engagement Initiative that will support distribution of naloxone, prevent overdose deaths, increase testing for HIV and viral hepatitis, and provide peer support services. This program will provide much needed services to 330,000 people.
- \$78 million for First Responder Training program and \$28 million for grants to prevent prescription drug and opioid overdose—increases for these SAMHSA programs will directly increase access to naloxone and prevent overdose deaths.
- \$28 million for Building Communities of Recovery, an increase of \$12 million, to expand peer recovery services, expanding access to shared life experiences and community knowledge from peers to program participants.

QUESTIONS:

Q: Do you think that we should schedule fentanyl and fentanyl analogues?

- It is a priority for this Administration to schedule the class of fentanyl-related substances. At the same time, we should make it easier to research Schedule I substances, and create

an off-ramp to de-schedule or lower the schedule of a fentanyl-related substance if data show it doesn't belong in Schedule I. These actions are all included in the Biden Administration's interagency agreement, which I support.

- We do know that the introduction of synthetic opioids like illicitly manufactured fentanyl has led to significant increases in overdose deaths. Of significant concern is the increasing contamination of the drug supply with fentanyl. This is leading to many individuals becoming exposed to fentanyl without even knowing or expecting it.
- Given the escalating overdose crisis and the negative impact of the COVID-19 pandemic, HHS experts came together to create a comprehensive Overdose Prevention Strategy meant to strengthen our primary prevention efforts and increase access to the full continuum of care and services for individuals with substance use disorder and their families.
- The availability of fentanyl underscores the need to expand access to quality prevention, treatment, recovery support, and harm reduction services. Ultimately, this is about saving lives.

Q: Can you talk about the importance of education on fentanyl contamination in the cases of drug overdose deaths?

- We know that the introduction of synthetic opioids like illicitly manufactured fentanyl have led to significant increases in overdose deaths. We also know that people are increasingly becoming exposed to fentanyl that has made its way into the drug supply.
- SAMHSA's First Responders-Comprehensive Addiction and Recovery Act Grants is one example of a program that works to train and provide resources to first responders and other key community members, distribute naloxone and fentanyl strips, and seek to reverse overdose deaths associated with fentanyl.
- We are proposing a \$22 million increase for this critical program.
- Other grants such as the State Opioid Response program and Comprehensive Opioid Recovery Centers (CORC) grant also support access to education, outreach, and the continuum of services people with opioid and/or stimulant use disorders need.

Food Safety

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA	1,520	1,730	+210

Talking Points:

- Today, we are in the midst of a **food revolution**—including how foods are produced, delivered, and handled.
- The budget proposes **\$1.7 billion** to invest in resources, staff, and technology that address rapid changes in human and animal food safety systems and human nutrition.
- Key investments include **protecting** in infant and toddler foods, **enhancing nutrition and food labeling**, and improving the security of the food **supply chain**. **For future disruptions.**

QUESTIONS:

Q: How will FDA's organizational changes improve its ability to carry out its food safety responsibilities?

- FDA is implementing a new, transformative vision for the FDA Human Foods Program, which will focus on protecting and promoting a safe, nutritious U.S. food supply that more quickly adapts to an ever-changing and evolving environment.
- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Q: Does the FY24 budget's proposed increases for Foods fund these organizational changes?

- The proposed increases cover needs identified in the Foods program even before the organizational changes began. As we continue to implement our transformative vision for the Human Foods Program and identify additional needs, we will come back to Congress.

Q: How will FDA's organizational changes improve its ability to carry out its food safety responsibilities?

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- FDA is implementing a new, transformative vision for the FDA Human Foods Program, which will focus on protecting and promoting a safe, nutritious U.S. food supply that more quickly adapts to an ever-changing and evolving environment.
- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Gun Violence and Community Violence

TALKING POINTS:

- Firearm injury is among the 5 leading causes of death for people aged 1–44 in the United States.
- Addressing the gaps in knowledge and identifying effective prevention strategies are needed to keep individuals, families, schools, and communities safe from firearm injury and death.
- Community violence directly or indirectly affects everyone in a community as people grieve for friends and neighbors and avoid engaging in neighborhood activities. In addition, violence creates strain on education, justice, and medical systems and weakens local business growth and prosperity, limiting community resources and preventing the achievement of other community goals.

QUESTIONS:

Q: Gun violence in the U.S. is at an all-time high, it is clearly a public health threat. Will you declare a PHE for gun violence?

- You're correct, this is a crisis—firearm injury is among the 5 leading causes of death for people aged 1–44 in the United States.
- The most important thing we can do is to continue to support prevention, education and research efforts across this country.
- We want to keep all options on the table, but we are not declaring a PHE at this time.

Harm Reduction

TALKING POINTS:

- HHS is fully committed to harm reduction as part of our comprehensive approach to address addiction and the overdose epidemic.
- More than 107,000 Americans died from a drug overdose in the 12-month period ending in August 2022. We must do everything we can to save lives.
- The Administration has a comprehensive overdose prevention strategy of primary prevention, harm reduction, treatment, and recovery support services.

QUESTIONS:

Q: Can HHS or SAMHSA grantees use any federal dollars to purchase and distribute needles?

- The FY 2023 Consolidated Appropriations Act Congress carried previous appropriations language that allowed for the purchase and distribution of needles so long as both local public health or local law enforcement deem it appropriate, or the State or local health department in concert with CDC has determined that the State or local jurisdiction is not experiencing or at risk for a significant increase in hepatitis infections or a HIV outbreak due to injection use.

Q: But I thought that the FY23 Omnibus included provisions that prevented grantees/states from using federal funds for the purchasing or distribution of drug paraphernalia?

- The Administration is focused on a comprehensive strategy, including prioritizing the use of evidence-based harm reduction strategies like providing naloxone and fentanyl test strips, **and what is allowed under federal, state, and local law.**
- SAMHSA is fully committed to harm reduction as part of its comprehensive approach to address addiction and the overdose epidemic. Our approach also includes expanding access to evidence-based prevention, treatment, recovery supports services.

Q: Is SAMHSA or HHS funding going to crack pipes in safe smoking kits? What else is in a safe smoking kit? When is it ever safe to smoke crack or meth?

- To answer your question directly, no federal funding will be used directly or through subsequent reimbursement of grantees to put pipes in safe smoking kits.
- The Administration is focused on a comprehensive strategy, including prioritizing the use of evidence-based harm reduction strategies like providing naloxone and fentanyl test strips, and what is allowed under federal, state, and local law.
- HHS is fully committed to harm reduction as part of its comprehensive approach to address addiction and the overdose epidemic. Our approach also includes expanding access to evidence-based prevention, treatment, recovery supports services.

Head Start -- Protecting Safety and Safeguarding Funds (Fraud)

TALKING POINTS:

- Protecting the health and safety of children and safeguarding federal funds are central to the Administration for Children and Families' (ACF) mission across programs.
 - HHS places the utmost priority on child health and safety; while rare, any incidents that jeopardize child safety are unacceptable.
 - HHS also takes seriously allegations of fraud, misuse and theft of federal funds.
- ACF issued guidance to Head Start programs on the requirements for reporting child incidents and provided training and technical assistance to Head Start programs on recognizing symptoms of abuse and neglect, using active supervision to create a safe environment for children, and understanding the responsibilities of a mandated reporter.
 - Recently, the Agency moved swiftly to suspend federal financial assistance in two cases based on the serious allegations of fraud, misuse and theft of federal funds.
- ACF is working diligently to implement the recommendations of the OIG in its report, *Child Safety in Head Start Programs*, and will continue to advance its rigorous national standards and reporting requirements.
 - We will continue to work with our programs to make any necessary improvements so that every child has the opportunity to thrive and reach their full potential in a safe and healthy environment. OHS will also continue to prioritize safeguarding federal funds, take all allegations about the misuse of federal funds seriously, and ensure any complaints are investigated and referred to the proper authorities if fraud is suspected.

QUESTIONS:

Q: Why did it take HHS three weeks to issue an emergency suspension in the New York case?

- The indictments did not include any allegations regarding children's safety or well-being.

Q: How many children may be impacted by the emergency suspension of these Early Head Start and Head Start programs?

- HHS is committed to minimizing the disruption to children and families impacted by this grant suspension. These grantees claimed to serve a combined total of approximately 740 children.

Q: What resources were available to assist impacted children and families?

- HHS set up a website and call hotline to assist families in finding a new early childhood program to meet their needs.

Q: What action has HHS taken to safeguard these grant funds following the indictment prior to issuing the emergency suspensions?

- On January 11, 2023, upon notification of the arrests and public release of the indictment, HHS implemented a funding lockdown on the Head Start grants for Project Social Care Head Start and NYC Early Learning Company.

Q: Does HHS' Administration for Children and Families take action on Head Start centers that have child safety incidents?

- Yes. Head Start grant recipients are required to immediately report any significant child safety incident to HHS. ACF recently clarified reporting requirements in program guidance. Following the report of an incident, ACF initiates a review to compile all evidence and facts surrounding the incident.
- Between 2016 – 2020, 95 percent of recipients who received a finding for a child safety incident demonstrated they corrected the issues that led to the incident. ACF will act to terminate the grant of a grantee that fails to correct the issue. More than one finding, failure to report, or failure to correct a serious or systemic child safety incident requires Head Start programs to compete for continued funding when the grant period ends.
- Staff and contractors who are found in violation of child safety policies are regularly disciplined or terminated by their Head Start agency.

Q: Were the teachers or administrators involved in the incidents called out in the report terminated or otherwise disciplined by ACF or their direct employer?

- ACF and individual Head Start programs take any incident that jeopardizes child safety very seriously. In most cases the employment of the staff persons involved directly in the incidents was terminated.
- Every Head Start agency must make systemic corrections for any incidents that occur with their program in a timely fashion. Often staff failings are evidence of broader systemic failures which must be corrected to ensure all children are kept safe. Grant recipients who do not demonstrate serious and timely commitments to correcting their safety systems risk immediate suspension of federal funding.

Q: How is ACF working to make sure children are safe in their programs?

- All children should have the opportunity to thrive and reach their full potential in safe and healthy settings that prepare them for school and life. While serious child safety incidents have occurred in Head Start programs, annually just 0.01% of children who attended Head Start programs from 2016-2020 were impacted by a serious incident.
- At the same time, ACF continues to prioritize efforts to improve the protection of children's safety. ACF takes a proactive approach to protecting child safety, providing technical assistance and training on supervision, preventing child abuse, and implementing policies and procedures to protect children.

- Head Start Program performance standards outline rigorous standards that must be met to ensure every child's safety. When an incident does occur, Head Start programs are required to report incidents to ACF, as well as state licensing and child protection agencies as appropriate.
- When child safety incidents are reported, ACF mobilizes resources to support the child and family involved, as well as to help the Head Start agency identify and remediate systemic failures that led to the incident.

Q: Why should Congress continue to fund a program that fails to keep all children safe?

- Head Start programs continue to be the gold standard for early childhood education and safety. Child safety incidents are rare, thanks to our robust federal oversight and rigorous health and safety requirements which support high quality services, as well as credentialed teachers and staff serving each of our centers.
- Head Start programs provide children one of the best starts in life. The Head Start program is a leader when it comes to early childhood practice related to infant mental health, parenting, dual language learning, curricular enhancements, caregiver-child interactions, dual-generation approaches, and other areas.
- Head Start programs serve nearly 1 million children and their families each year in urban, suburban, and rural areas in all 50 states and DC.

Head Start - Vaccine Mandates

TALKING POINTS:

- Head Start programs are critical supports for families and children and we are committed to ensuring they remain safe and open.
- Program closures create instability for vulnerable families who depend on the program, impede Head Start families from participating in the workforce, and impose financial hardship on low wage workers.
- In January 2023, ACF published its evidence-based Final Rule on COVID-19 mitigation, which removed the universal masking requirement but did not change vaccination or testing requirements. The vaccine and testing requirements remain under review until a final rule is published to address those provisions of the Interim Final Rule with Comment Period
- The CDC continues to recommend that children ages 6 months and up be vaccinated against COVID-19. Vaccination remains the most effective way to protect individuals and the people they live and work with from getting COVID-19 – especially in care settings like Head Start.

Health Exchange Fraud

- HHS is committed to protecting taxpayer funds while balancing the burden on consumers, employers, and other individuals and entities involved in the Federally-facilitated exchange (FFE) and State-based exchanges (SBEs).
- As such, HHS has implemented a number of strategies to oversee the program integrity of Advance Payments of the Premium Tax Credit (APTC) to prevent and address instances of potential fraud.

Specifics

- As previously recommended by the GAO, HHS completed an Exchange Fraud Risk Assessment, leveraging the GAO's fraud risk framework. HHS has used this framework to identify and prioritize key areas for potential risk and mitigation activities in the Federally-facilitated exchange.
- In November 2022, HHS announced the first improper payment rate for APTC made using the Federally-facilitated exchange platform, which was less than one percent (0.62 percent) for Benefit Year 2020.
- HHS requires State-based exchanges to conduct a defined set of oversight activities, and tracks and monitors how State-based exchanges establish program integrity standards that comply with Exchange-related policy and operational requirements set forth in statute, regulations, and guidance.
- CMS regulations specify a set of eligibility verification requirements that all Exchanges, including State-based exchanges, must follow. These regulations, developed and finalized through a public comment process, allow flexibility for certain eligibility verification requirements as to how Exchanges should meet the relevant verification requirement.
- HHS monitors State-based exchange compliance with program integrity standards through numerous means, including requiring SBEs to submit annual independent external programmatic audits conducted by an independent auditing entity. State-based exchanges must inform HHS of any audit findings and submit corrective action plans to address open findings. HHS reviews the audit results and monitors open audit findings until they are resolved.
- Finally, all State-based exchanges are required to submit documented plans demonstrating that they have a comprehensive oversight and monitoring program to ensure program integrity, which includes policies and procedures to identify incidents of fraud, waste, and abuse, as required under Section 1313(a)(5) of the ACA.

Hepatitis C

(Dollars in Millions)

	FY 2024	FY 2024-2028 (5-year)	FY 2024-2033 (10-year)
National Hepatitis C Elimination Program Cost	1,134	11,337	11,337
Medicare Impact	183	1,177	984
Medicaid Impact	-1,130	-6,330	-7,180
National Hepatitis C Elimination Program Net Cost	-187	6,184	5,141

TALKING POINTS:

- **Eliminate:** We can eliminate hepatitis C in the United States over the next 5 years at minimal cost. The program will expand screening, testing, treatment, prevention, and monitoring of hepatitis C from 418,000 to 1.5 million individuals with a goal of eliminating hepatitis C in the United States.
- **Equity:** More than 2 million Americans are chronically infected with hepatitis C, including a disproportionate number of non-Hispanic Black and American Indian and Alaska Native individuals, who also experience other health disparities.
- **Rising rate of infection:** From 2010 to 2020, rates of acute hepatitis C quadrupled among adults aged 20–39 years, mirroring increasing rates of overdose deaths fueled by the nation's opioid and methamphetamine crises.
- **Curative Treatment:** Untreated, hepatitis C can cause advanced liver disease, liver cancer, and death. An 8 to 12-week course of oral direct acting antivirals cures hepatitis C in more than 95% of people. Curative treatment prevents ongoing transmission, reduces the incidence of liver cancer, saves lives, and is cost effective.
- **Prevention:** Implementation of the program will increase the number of people treated for hepatitis C from 418,705 to 1,500,452 over 5 years, preventing hundreds of thousands of severe illnesses, tens of thousands of serious complications, and many thousands of lives over the next decade – at minimal net cost.

QUESTIONS:

Q: How will this program work?

- The Program includes a national subscription model to expand access of direct acting antivirals to Medicaid beneficiaries, justice-involved populations, uninsured individuals, and American Indians and Alaskan Natives receiving care through the Indian Health Service, tribal health, or urban Indian health programs. The subscription model will include all manufacturers that offer competitive prices.
- For Medicaid beneficiaries, the federal government will pay 100% of the medication costs through the subscription program. The medications will be made available

through established distribution channels, including mail order pharmacies, retail pharmacies, and 340B hospital and clinic pharmacies. The model will include a low burden eligibility check, likely at the provider level, to avoid waste, errors, and fraud.

- For Medicare beneficiaries, the federal government will cover 100% of cost-sharing for all Medicare Part D beneficiaries receiving covered treatment. Medicare will also adopt a program of quality measurement and improvement to drive uptake of hepatitis C testing and treatment.
- Private insurers will be required to cover hepatitis C testing and curative hepatitis C treatment by reducing coverage denials and meeting network adequacy requirements. Insurers will also limit out-of-pocket costs for these medications; for example, by including coverage prior to the deductible being met.

Q: Is this a cure for hepatitis C?

- There is still no vaccine for hepatitis C. The program will include support for vaccine research and preventive services, which has been shown to reduce reinfection rates substantially.

Q: How will HHS identify and attract currently infected individuals to get screened, tested, and treated?

- The Program will substantially expand screening strategies and settings, especially for high-risk populations. For instance, it will support universal screening in primary health care settings as part of routine care, including through automatic prompts to clinicians in electronic health records.
- The program will also develop educational resources for providers and the public to increase awareness of hepatitis C, screening recommendations, and treatment options.
- Other approaches will include expanding the number of providers who can screen and treat hepatitis C using proven and innovative telehealth methods and increasing the number of community health workers and case managers who can successfully link people to care. CDC and HRSA will provide grants to state and local health departments to support the funding for community-based providers. The Program will also support mobile treatment capabilities.
- The Program will accelerate the commercialization of diagnostic tests that are available outside of the United States, specifically point-of-care RNA diagnostics and hepatitis C virus core antigen laboratory assays.

Q: How many non-Hispanic Black and American Indian and Alaska Native individuals, experience other health disparities?

- Hepatitis C disproportionately affects certain populations, many of which experience other health and social inequities -- including those who are uninsured, American Indian and Alaska Native persons, non-Hispanic Black persons, those caught up in the opioid crisis, and baby health records. boomers who were infected in pre-1993 blood transfusions. From 2010 to 2020, rates of acute hepatitis C quadrupled among adults aged 20–39 years, mirroring increasing rates of overdose deaths fueled by the nation's opioid and methamphetamine crises.

Q. Which parts of HHS will carry out the work on this program?

- The Office of the Assistant Secretary for Health (OASH) will administer and coordinate this whole-of-government program. With a robust organizational structure in place, OASH is well positioned to ensure cross-departmental and intergovernmental collaboration and transparency. In similar capacity, OASH also leads and coordinates a cross-agency, federal government-wide the Ending the HIV Epidemic in the U.S. (EHE) initiative. OASH will also be responsible for providing an annual report to Congress.

HIPAA

TALKING POINTS:

- Ensuring individuals have access to their health information and protecting patient privacy is of the utmost importance.
- OCR expects to receive over 33,000 HIPAA complaints this year and has seen an increase in large breaches (over 500 people).
 - HIPAA complaints increased 39 percent from 2017 to 2022; HIPAA breach cases alone have increased 259 percent during the same time.
- OCR's proposed budget increase to \$78 million will also allow the division to fully enforce the law and keep up with the growing workload of cases through hiring additional investigators.
- OCR is also currently engaged in the rulemaking process on the HIPAA Privacy Rule, which established federal standards for the protection of protected health information, and we look forward to your feedback during that process.

IHS - Provider Abuse

TALKING POINTS:

- There is no more important priority at IHS than the protection of patients – especially our most vulnerable patients – from abuse and instilling a culture of accountability. IHS must be able to continue to foster trust and instill confidence in the communities it serves.
- IHS has taken strides to increase safety across the board during this Administration.
 - The IHS Anti-Abuse policy is nearing completion. This policy will increase protection for all patients, and will cover all employees, and all types of abuse.
 - The IHS is developing and implementing a uniform credentialing and privileging policy.
 - The IHS has also fully implemented Safety Tracking & Response (I-STAR) across the Agency to provide real time data on any reported provider abuse, which will result in immediate action to investigate any provider abuse allegations.
- We can still do more. We continue to review our systems and identify gaps that could lead to vulnerabilities. IHS is committed to working with Congress, HHS OIG and local enforcement agencies, and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of the patients under our care. The budget includes an additional +\$12 million for IHS Direct Operations to support critical management and oversight functions at IHS, including implementing recommendations to prevent abuse and ensure patient safety.

QUESTIONS:

Q: Can you speak to the lessons learned after the Dr. Weber tragedy?

- My heart goes out the victims of this unfortunate tragedy. Abuse and other forms of criminal misconduct should not be tolerated
- HHS Employees are encouraged to report any suspected unethical or criminal behavior. Any transgressions that endanger the people we serve or violate the public trust will be held accountable.
- We are committed to maintaining transparency with Congress as IHS and other HHS officials work to implement important and necessary changes to ensure the safety of our workplace and patients.
- The safety and wellbeing of children in the care of HHS is among our most important responsibilities and we will continue to be vigilant.

Q: What does IHS have to say to the victims of provider abuse?

- The IHS acknowledges the trauma suffered by the victims of sexual abuse within our agency is unacceptable. These actions are reprehensible, and we sincerely regret the harm caused to those involved.
- We will do all we can to improve and sustain the culture of care throughout the IHS. The agency is committed to working with Congress and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of every child. Together, we are moving forward in delivering quality care to achieve the IHS mission to raise the physical, mental, social and spiritual health of American Indians and Alaska Natives to the highest level

Q: What are the 11 actions that IHS intends to accomplish with the goal of removing IHS from the GAO's High-Risk List?

- Misconduct and Performance Policy and Training Review
- Design Governing Board Standardization
- Assess Needs of Patient Populations
- Document Oversight of Facility Budgets
- VA and IHS MOU Performance Measures
- Strategic Plan Implementation and Progress Tracking
- Improve Internal Communications
- Document Oversight of Leadership Training
- Design a Policy Review Process
- Create a Culture of Compliance
- Improve Oversight of Regional and Area Human Resources Offices

IHS - Advance Appropriations

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Total IHS Funding	7,105	9,650	+2,545*

* Represents an increase of 36% over FY23 enacted

TALKING POINTS:

- We are especially grateful for your work providing IHS advance appropriations in the FY 2023 bill – this was truly a historic achievement that will greatly improve the lives of Native American families throughout Indian country.
 - Indian Country has been asking for more stability to address the persistent health disparities suffered by AI/ANs, and together, we finally delivered.
- Advance appropriations represent an important step towards securing stable and predictable funding to improve the overall health status of AI/ANs, and ensuring that the disproportionate impacts experienced by tribal communities during government shutdowns and continuing resolutions are never repeated.
 - We are already seeing the benefits of advance appropriations in action – we have heard from health facilities about benefits in improved planning and staff job security.
- IHS remains committed to upholding promises it has made to both Congress and Indian Country to continue to increase accountability and improve the quality of care for patients.

QUESTIONS:

Q: What about mandatory funding?

- Looking beyond this budget year, the Administration continues to support full mandatory funding for IHS as the more appropriate long-term funding solution for the agency.
- We will continue to work collaboratively with Tribes and Congress to move toward sustainable, mandatory funding.
- Until this solution is enacted, it is critical that Congress continue to prioritize advance appropriations for IHS through the discretionary appropriations process to ensure funding for healthcare services and critical facilities activities are not disrupted.
- Beginning in FY 2025, the budget would make all funding for IHS mandatory. Funding would grow automatically to account for a number of factors.
 - We believe that a change of this magnitude is needed to meet the moment and deliver for Indian Country.

IHS – Contract Support Costs

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Contract Support Costs*	969	1,168	+199

*The budget proposes mandatory funding for Contract Support Costs in FY 2024

TALKING POINTS:

- We are aware of recent court rulings that would require IHS to pay Contract Support Costs on portions of Tribally-operated Health Programs funded by third party revenues like Medicare and Medicaid reimbursements.
- This change could significantly increase the amount of Contract Support Costs that IHS provides to Tribally-operated Health Programs.
- If these rulings are upheld, HHS will work to implement them as expeditiously as possible.

QUESTIONS:

Q: Does the FY 2024 Budget take the cost of implementing these rulings into account?

- The funding estimate for Contract Support Costs in the budget does not reflect the impact of implementing the 9th and 10th circuit court rulings, as they are not yet settled case law.
- HHS is actively monitoring the situation and analyzing potential costs. We will keep Congress apprised of any changes in Contract Support Costs as a result of the rulings.

IHS - High-Risk List

TALKING POINTS:

- IHS is committed to addressing and correcting past failings. We also remain committed to transparency and accountability and are continually working to sustain and improve the culture of care throughout the Agency.
- In 2021, IHS developed an action plan to meet the GAO's criteria for removal from its high-risk list. Since that time, the agency has been working to address actions to accomplish by the end of June 2023. IHS leadership is committed to making progress on addressing GAO's recommendations. These efforts built the foundation for the agency's 2023 work plan.
- The Department and the Agency are committed to working with Congress and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of every patient. Together, we are moving forward in delivering quality care to achieve the IHS mission to raise the physical, mental, social and spiritual health of American Indians and Alaska Natives to the highest level.

QUESTIONS:

Q: What are some of the actions that IHS intends to accomplish with the goal of removing IHS from the GAO's High-Risk List?

- Misconduct and Performance Policy and Training Review
- Design Governing Board Standardization
- Assess Needs of Patient Populations
- Document Oversight of Facility Budgets
- VA and IHS MOU Performance Measures
- Strategic Plan Implementation and Progress Tracking
- Improve Internal Communications
- Document Oversight of Leadership Training
- Design a Policy Review Process
- Create a Culture of Compliance
- Improve Oversight of Regional and Area Human Resources Offices

Q: GAO highlighted that IHS faces workforce challenges; their overall vacancy rate for clinical care providers was 25 percent at one point. What has IHS done to resolve this issue?

- IHS has strengthened its relationship with academic institutions through fellowships, residencies and clinical rotations that attracted talented practitioners focused on generating positive change in Indigenous communities.

- IHS signed a new MOU with the VHA aimed at improving the health status of AI/AN veterans.
- IHS has supported public health workforce activities to bolster the capacity of tribal communities to respond to future emergencies.

Q: What has IHS done to address some of the concerns with personnel processes and systems?

- Implemented a nationwide electronic provider credentialing system that modernizes provider credentialing and privileging within federally-operated hospitals and clinics.
- Implemented an employee relations case tracking system to manage nationwide employee relations activities.
- Implemented an electronic Security Manager System to track personnel background investigations.
- Established a standardized procedure for determinations of unsuitability from a background investigation.

Institution for Mental Disease (IMD) Waivers

TALKING POINTS (IMDs AND CRISIS STABILIZATION):

- Strengthening behavioral health care is a top priority for the Biden-Harris Administration. That's why last year, as part of the National Tour to Strengthen Mental Health, I traveled along with other HHS leaders across the country to hear directly from Americans about the mental health challenges they're facing and engage with local leaders to strengthen the mental health and crisis care systems in our communities.
- Under current law, Medicaid generally does not pay for services rendered to beneficiaries aged 21 to 64 who are patients in psychiatric institutions with more than 16 beds, referred to in Medicaid as "institutions for mental disease" (IMDs).
- Crisis stabilization services are critical to those experiencing a behavioral health crisis, and HHS shares your goal of ensuring Medicaid beneficiaries have access to a continuum of crisis stabilization services. CMS has worked within the confines of the law to provide states with flexibility to increase access to these services. For example,
 - o CMS has approved Medicaid section 1115 demonstrations that allow state Medicaid programs to pay for services provided to individuals with serious mental illness or serious emotional disturbance or substance use disorder who are short-term residents in an IMD.
 - o Similarly, managed care organizations are permitted to reimburse up to 15 days per month of treatment in IMDs.

If Pressed on Qualified Residential Treatment Programs

- Children in foster care should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. CMS is committed to ensuring children with unique health needs receive high-quality care in the most appropriate setting permissible under the law.

QUESTIONS:

Q: Are crisis stabilization programs subject to the Medicaid IMD exclusion?

- Each state is responsible for determining whether a facility is an IMD. If a state Medicaid agency determines that a facility is an IMD, federal financial participation generally would not be available for any services provided to Medicaid beneficiaries ages 21-65 while residing in that facility. Medicaid does permit payment for inpatient psychiatric hospital services provided to those over the age 65 or under the age 21.

Q: Can you explain how the IMD exclusion doesn't violate parity laws? Enrollees are covered if they stay in non-psychiatric facilities that have more than 16 beds. Are private insurance plans allowed to make this exclusion?

- The payment exclusion for Medicaid services provided to beneficiaries in IMDs is a statutory prohibition established by the Congress in 1965 and therefore beyond the scope of existing HHS authority. Under this broad exclusion, federal financial participation is generally unavailable for the cost of services (regardless of whether the services address physical or mental health) provided either inside or outside the IMD while the individual is a patient in the facility. The full range of covered services, including mental health and substance use disorder services, could be paid by Medicaid when beneficiaries are in facilities that are not IMDs.

Q: Do you believe that children in Qualified Residential Treatment Programs with more than 16 beds should be able to keep their Medicaid coverage?

- Children should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. Placement in a Qualified Residential Treatment Program that is an IMD does not impact Medicaid eligibility.
- While the Medicaid statute prohibits states from receiving federal financial participation for services delivered to most individuals residing in an IMD, states can apply for a time-limited serious mental illness/serious emotional disorder 1115 demonstration to receive Medicaid payment for services provided to children in Qualified Residential Treatment Programs with more than 16 beds.

Infant Formula

TALKING POINTS:

- Ensuring that safe and nutritionally adequate infant formula is available to parents and caregivers across the country is a top priority of the Department.
- That is why during the shortages—HHS invoked the Defense Production Act to ensure rapid increase in supply. We flew in 13.7 million 8-oz bottle equivalents of infant formula, facilitated 11 flights to fly in formula to the United States, and imported more than 97.9 million 8-oz bottle equivalents of infant formula.
- FDA is focused on hiring additional staff, modernizing scientific requirements, and streamlining review processes for infant formula.
- This budget will support FDA efforts to implement new authorities provided by the FY23 omnibus including requiring prompt notifications of disruptions to manufacturing, requiring redundancy risk management plans to enhance resiliency and mitigate future supply chain disruptions, increasing the frequency of inspections, and developing a National Strategy on Infant Formula.

Perrigo Recall Talking Points:

- Perrigo, an infant formula manufacturer, recalled certain lots of its Nestle Gerber GoodStart Infant Formula produced at its Eau Claire, Wisconsin facility.
- The FDA is not currently aware of any Cronobacter-related illnesses associated with the recalled products.
- The recall is the result of a recent FDA inspection at the facility where investigators discovered the company found Cronobacter in products it produced in January. The agency also learned that other products were produced at the facility in the same timeframe and the agency did not have confidence, based on the manufacturing procedures, that the product was contamination free.
- We don't expect this recall to have a significant impact on current powdered infant formula supply. The Administration has worked to strengthen the infant formula supply chain by providing more products options for parents and caregivers.
- Earlier this month [March 8], FDA sent a letter to the infant formula industry asking for voluntary notifications of products that tested positive for certain types of bacteria and has not left the company's control. The FDA is seeking, but currently does not have, authority from Congress to require infant formula manufacturers notify the agency with this information.

QUESTIONS:

Q: How will FDA ensure the infant formula crisis does not happen again?

- FDA continues efforts to ensure the availability of safe, nutritious infant formula.
- The FY 2024 President's Budget includes a request for an additional \$10 million, for a total of \$21million, to support additional hiring of staff, as well as IT investments to better address current and emerging infant formula safety and supply issues.

- This budget will support FDA efforts to implement new authorities provided by the FY23 omnibus including requiring prompt notifications of disruptions to manufacturing, requiring redundancy risk management plans to enhance resiliency and mitigate future supply chain disruptions, increasing the frequency of inspections, and developing a National Strategy on Infant Formula.
- FDA also released a transition plan guidance for industry to outline a path for interested manufacturers that are marketing infant formulas in the U.S. under enforcement discretion to bring those products into compliance with U.S. requirements, helping the U.S. continue to diversify its infant formula market. As part of this plan, the Agency also continues to exercise enforcement discretion for certain manufacturers to import safe and nutritionally adequate infant formula.
- FDA also continues to work with industry to increase the volume of infant formula through normal production channels, as well as increase its monitoring of online marketplaces for fraudulent infant formula products.
- FDA also sent a letter to the powdered infant formula industry calling for prompt action to improve processes and programs to enhance safety measures.

Q: How will FDA's organizational changes improve its ability to oversee the infant formula supply chain and carry out its food safety responsibilities?

- FDA is implementing a new, transformative vision for the FDA Human Foods Program, which will focus on protecting and promoting a safe, nutritious U.S. food supply that more quickly adapts to an ever-changing and evolving environment.
- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Inflation Reduction Act (IRA)

TALKING POINTS:

- Thanks to the Inflation Reduction Act, we finally have the authority to get American families the lower prescription drug costs they deserve.
- At the beginning of this year, we implemented the \$35 cost-sharing cap for insulin in Medicare Part D and eliminated cost-sharing under Part D for recommended, preventive vaccines.
- We are also pleased that the IRA included a provision to expand low-income assistance and to cap Part D annual out-of-pocket drug costs at \$2,000 in 2025.
- Earlier this month, we released guidance outlining how we will approach the law's landmark provisions permitting Medicare to negotiate prices for the first time, seeking comment on many key policies.

INSULIN PRICING TALKING POINTS:

- As of this week, all three of the leading insulin producers in America have heeded President Biden's call to reduce their prices and cap the cost of insulin to \$35 per month.
- This is a major victory for seniors and working families. For far too long, American families have been crushed by drug costs many times higher than what people in other countries are charged for the same prescriptions.
- Last August, President Biden signed into law the Inflation Reduction Act, which for the first time allows Medicare to negotiate lower prescription drug prices for seniors, caps the cost of insulin at \$35. During his State of the Union, the President made clear that this life saving benefit should apply to everyone – no American should have pay more than \$35 for insulin. And he called for extending the \$35 monthly cap on insulin to all Americans.

QUESTIONS:

Medicare Drug Price Negotiation Program

Q: Won't the Medicare Drug Price Negotiation Program lead to manufacturers increasing the launch prices for new drugs?

- Manufacturers use many factors when considering their launch prices and will price their drugs at the price they believe the market will bear.
- It's also important to note that a drug cannot be eligible for negotiation until it has been FDA-approved for at least 7 years and a biological product cannot be eligible for negotiation until it has been FDA-licensed for at least 11 years.
- The Congressional Budget Office didn't estimate that the new Drug Price Negotiation program would have a significant impact on launch prices.

Q: Will drug price negotiation have a chilling effect on manufacturers seeking a second or third indication for an orphan drug?

- Drugs selected for negotiation will have been on the market for quite some time and will be high expenditure drugs.
- The law requires that at least 7 years, for drugs, or 11 years, for biologicals, must have elapsed between the selected drug publication date and the FDA approval or licensure, as applicable.
- We support innovation and believe it is vitally important that beneficiaries have access to innovative new therapies.
- Increased competition as a result of drug price negotiation will encourage drug makers to innovate in order to stay competitive and broaden their target patient populations, including orphan diseases.

Q: Won't drug price negotiation crush innovation and kill hundreds of new cures? Studies have found that the IRA's negotiation provision would kill up to 342 cures.

- We support innovation and believe it is vitally important that beneficiaries have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.
- The Negotiation Program will make drugs more affordable for people with Medicare. We're also expecting negotiation to encourage drug makers to create business models to stay competitive, fostering the development of new treatments and delivery methods.

Q: What concrete steps does the Administration plan to take in order to implement and enforce the legislation's ban on the use of discriminatory comparative effectiveness research (i.e., QALYs)?

- The law requires that we not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who are elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. We will follow the law.

Medicare Part B and Part D Inflation Rebates

Q: How will HHS plan for and respond to drug shortages or severe supply chain disruptions of Part B and Part D rebatable drugs?

- The law requires CMS to waive or reduce the inflation rebate when drug shortages or certain supply chain disruptions occur.
- CMS is soliciting comment on this issue, and intends to design a final policy that preserves access, while not creating perverse incentives for drug companies to sustain or create drug shortages.

Q: Won't the Medicare Prescription Drug Inflation Rebate Program lead to manufacturers increasing the launch prices for new drugs?

- Our understanding is that manufacturers use many factors when considering their launch prices and price their drugs at the price they believe the market will bear.

- For too long, Americans have faced skyrocketing prescription drug prices.
- Thanks to the law, prescription drug companies will pay a rebate for increasing their prices above inflation, paid into the Medicare Trust Fund.
- This policy will strengthen the Medicare program for generations to come.

Q: Are 340B acquired units being removed from the Part D inflation rebates?

- The Inflation Reduction Act sets clear parameters and timeframes for how to treat 340B drugs as HHS implements inflation rebates. We will follow the law.
- The Inflation Reduction Act requires that 340B units be excluded from calculating Part D inflation rebates beginning in 2026. We will follow the law.

Implementation Funding

Q: How is HHS planning to spend the \$3 billion in implementation funding provided by the Inflation Reduction Act for the Drug Price Negotiation Program?

- We're still in the early stages of the implementation process.
- The new Drug Price Negotiation Program requires a great deal of new work by CMS.
- We're using the funding to hire new staff, bring on contractors, and develop and modify systems.
 - Internal Information: To date, CMS has spent \$45 million (FY 2022 and so far in FY 2023). ASFR is working with CMS to have a long-term spend plan. The breakdown is below:

IRA Sections	FY 2022 Actuals	FY 2023 Spend plan	FY 2023 Obligations
Section 11004	\$ 1,702,272	\$ 124,291,357	\$ 23,009,975
Section 11101	\$ 3,197,048	\$ 15,743,023	\$ 4,158,849
Section 11102	\$ -	\$ 12,037,324	\$ 1,722,262
Section 11201	\$ 3,726,526	\$ 48,743,155	\$ 3,534,535
Section 11202	\$ -	\$ 10,555,586	\$ 2,293,231
Section 11406	\$ 1,500,000	\$ -	
Total	\$ 10,125,846	\$ 211,370,444	\$ 34,718,852

- This information is part of an open Oversight request from the Committee on Energy and Commerce. The information is not public yet, but a response with the above information will be provided prior to next week's hearing with this committee.

Q: What specific measures does the administration plan to undertake in order to prevent waste, fraud, and abuse with respect to the implementation funding?

- We take our responsibility to protect taxpayer dollars very seriously. We are vigilant about how we are spending the funding to head off waste, fraud, and abuse, just as we do with implementing other programs.

Insurance Affordability and Coverage Gap

TALKING POINTS:

- The Biden-Harris Administration is committed to keeping high-quality healthcare coverage affordable, accessible, and permanent for all Americans.
- The Affordable Care Act has reduced the number of uninsured Americans to an all-time low and enhanced subsidies extended by the Inflation Reduction Act have made Marketplace coverage even more affordable and accessible for millions of Americans.
- Building on these successes, the budget makes permanent the enhanced premium tax credits so that consumers can keep high-quality, low-cost coverage.
- This budget extends coverage to the 2 million low-income individuals in states that have not expanded Medicaid by providing \$200 billion for a Medicaid-like coverage option.

QUESTIONS:

Q: How exactly would HHS close the coverage gap in States that have not expanded Medicaid?

- The budget would fulfill the intention of the Affordable Care Act by providing premium-free plans to individuals below 138 percent of the poverty level in states that have not expanded Medicaid, potentially decreasing the number of uninsured individuals by over two million.

Q: What is the Administration doing to make health insurance more affordable for Americans?

- The enhanced premium tax credits, which were extended through 2025 under the Inflation Reduction Act, have played a vital role in making coverage more affordable for millions of Americans by eliminating the required premium contribution for very low-income individuals and families and limiting the maximum income contribution towards benchmark Marketplace plans to 8.5 percent of income.
- The enhanced premium tax credits also made coverage more affordable for the middle-class by lifting the eligibility cap for these tax credits, which was previously set at 400 percent of the poverty level.
- Also, in 2022, the Administration finalized regulations that fixed the “family glitch,” which finally closed a loophole that prevented over a million Americans from obtaining coverage or seeing their coverage become more affordable.

Q: What will HHS do to make sure that uninsured Americans know about these affordable coverage options?

- The Biden-Harris Administration has quadrupled the number of Navigators to help hard-to-reach and traditionally marginalized groups enroll in quality, affordable coverage.

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- HHS has invested over \$1.2 billion into Navigators and outreach campaigns since 2021, which connected people with high-quality, affordable health care. These historic investments have helped result in the lowest uninsured rate in our nation's history.
- In this budget proposal, we are doubling down on these investments to ensure people get the insurance they need by allocating \$141.2 million available for Navigators and Assisters and budgeting over \$280 million for other forms of outreach.

LGBTQ Youth

TALKING POINTS:

- Gender affirming care is a standard of care recognized by every major medical association, which included 1.3 million providers. It's also mental health and suicide prevention.
- The current medically-accepted standard of care, WPATH SOC8, was developed by the top medical and scientific experts in transgender health.
- The ideologically-driven attacks on gender-affirming care do not account for the best available science and evidence on appropriate healthcare services for transgender people.
- Likewise, gender affirming care is an integral part of child centered welfare programs especially those for vulnerable children and youth. This budget supports prohibiting child welfare agencies from discriminating against current or prospective foster or adoptive parents or a child in foster care on the basis of sexual identity, gender identity, or expression.

QUESTIONS:

Q: What is a woman?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- Support youth and families; HHS commitment to advance safety and support for LGBTI+ youth. Access to gender affirming care, when medically necessary can be lifesaving.
 - Ensuring such access is the law.

Q: How many genders are there?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- At HHS, we are committed to advancing health equity for people of all genders. Health equity is defined by HHS Healthy People 2030 as the "attainment of the highest quality of health for all people." We work toward that goal every day.

Q: Does HHS support irreversible genital surgeries on children?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

Q: Is HHS funding gender affirming care?

- The Department is committed to removing discriminatory barriers to coverage for all because it can lead to improved health outcomes for all, including those in the LGBTQI+ community.
- HHS will continue to interpret and enforce section 1557 of the ACA and its protections against sex discrimination to prohibit discrimination on the basis of sexual orientation and gender identity in all aspects of health insurance coverage to which Section 1557 applies.

Q: Does HHS support “biological boys” playing on girls sports teams?

- In my role as Secretary of Health and Human Services, I am focused on making sure people have health care, period. HHS does not have a role in youth sports.
- [Optional]: The harm caused by these state laws is very clear: trans youth are more likely to experience social isolation, loneliness, depression, and are more likely to utilize tobacco, alcohol, and other drugs – all of which we know are decreased by participation in school sports.

Q: Does HHS support irreversible and experimental medicine on children such as puberty blockers?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

LIHEAP/LIHWAP

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Base Funding	4.0B	4.1B	+111M
Supplementals	2.1B	100M	-2.0B
Total LIHEAP Program Level	6.1B	4.1B	-1.9B

* LIHWAP's last funding was in FY21 at \$638 million under the Consolidated appropriations Act of 2021. The American Rescue Plan appropriated an additional \$500 million in emergency funds to LIHWAP

TALKING POINTS:

- We recognize that LIHEAP is an essential program for Americans, especially for older adults and people with disabilities who are particularly vulnerable to the effects of cold.
- Likewise, LIHWAP benefits vulnerable households that pay the greatest proportion of their income towards their home drinking water and wastewater services. Water, heat, and especially in a changing climate – cooling – are basic human rights that the Department is proud to help make accessible for all.
- We have made historic investments in the program during the Biden Administration.
 - In FY2023, Congress appropriated more than \$6.1 billion for LIHEAP.
 - In the past month we have disbursed over \$1.5 billion of these funds to our 206 LIHEAP grant recipients – a lifeline for many seeing record cold and snowfalls this winter.
- The Budget requests \$4.1 billion for LIHEAP, an increase of \$111 million in base funding compared to FY 2023
- We are looking forward to continuing to partner with you to ensure we meet the critical mission of these programs by providing it with strong funding levels.

QUESTIONS:

Q: There has been some reporting and concern that states will not be able to spend their LIHWAP disbursements in time and leave money on the table. Can you speak to what the Department is doing to support states in this effort?

- We are conducting Spend Down Calls with each state, to provide TTA and help identify solutions to maximize spending when needed. We want to make sure states know about and are able to talk through promising practices that can help increase their spending rates before we take back any funding for reallocation.

Q: Why did it take HHS a couple of months to release these funds?

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- The delay in releasing the funding is largely due to the fact LIHEAP funding was split across multiple funding streams in the final budget, including three different supplementals.
- HHS worked to find the most efficient and expedient way to release funding while minimizing the reporting burden to the grant recipient to the greatest extent possible.

Long Term Care

TALKING POINTS:

- The budget invests an additional \$150 billion in Medicaid home and community-based services over 10 years, enabling older adults and people with disabilities to remain in their homes and stay active in their communities.
- The Medicaid investments are complemented by a robust agenda to **improve the safety and quality of nursing home care**, including efforts to improve ownership transparency, increase inspections of low-performing nursing homes, and expand financial penalties for substandard facilities.
- The budget makes a \$566 million discretionary investment in CMS's survey and certification program to provide **adequate funding for nursing home inspections** and address the backlog of complaint surveys, a \$159 million increase.

QUESTIONS:

Q: CMS is proposing a number of mandatory nursing home proposals. Why is an increase in discretionary funding also necessary?

- Since FY 2015, CMS has seen an increase in the overall number of nursing home complaints and instances of high-level violations, both of which require additional survey resources. Additional resources allow CMS and state survey agencies to maintain a more proactive, rather than reactive, oversight posture that promotes patient safety and quality.

Q: Won't penalizing poor performing facilities strain resources and limit a facility's ability to provide high-quality care, further perpetuating the issue?

- Tens of billions of federal taxpayer dollars flow to nursing homes each year, and too many continue to provide poor, sub-standard care that leads to avoidable resident harm.
- Federal taxpayer dollars should not flow to nursing homes that are unsafe.

March In Rights

TALKING POINTS:

- March-in authority is a powerful tool designed to ensure that the benefits of the American taxpayer's investment in research and development are reasonably available to the public.
- It is critically important for us to thoroughly understand where the boundaries of that authority lie in order to carry out that authority effectively.
- Consistent with President Biden's Executive Order on Promoting Competition in the American Economy, the Department of Commerce has not finalized any provisions on march-in rights in the proposed rule "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions" that would have prohibited the government's use of march-in rights solely on the basis of product pricing.
- As a first step in reviewing its march-in authority, HHS, DOC, and other agencies will develop a framework for implementation of the Bayh-Dole march-in provision that clearly articulates guiding criteria and processes for making determinations, including where pricing is a factor in agencies' assessments.

Questions

Q: What is the total cumulative support provided by the NIH to Moderna, including for clinical trials? How much money has the US government provided to Moderna to research, develop and distribute the COVID-19 vaccine?

- HHS/NIH/NIAID has provided no direct financial support to Moderna for the development of the mRNA-1273 COVID-19 vaccine.
- NIAID scientists collaborated with Moderna to design and test the mRNA-1273 COVID-19 vaccine.
- NIH did not fund Moderna directly but NIH fully funded Phase I clinical trials through existing clinical trial networks and supported extramural institutions during OWS-funded Phase 3 clinical trials.
- Note that the COVID-19 vaccine product licensed and manufactured by Moderna contains IP beyond the patents shared with NIH. This includes IP that belongs to Moderna, e.g., the lipid nanoparticle technology.

Q: What was HHS thinking when negotiating these patents?

- HHS's top priority during the COVID-19 pandemic was establishing safe and effective medical countermeasures that would save lives and prevent human suffering from COVID-19.
- This strategy included leveraging a preexisting partnership with Moderna and the NIAID Vaccine Research Center (VRC) that had been established for the development of mRNA-based vaccine candidates against selected pathogens, including the coronavirus that causes Middle East respiratory syndrome (MERS).
- This partnership resulted in the development of an investigational vaccine against MERS.
- At the time of negotiations, it was unclear whether mRNA-based vaccines would be successful, NIH priorities were in line with what NIH has expertise in, the science –

ensuring the vaccine worked and those results were reliable, therefore NIH negotiated according to the science and the pressing public health need that:

- A single IRB would be used for all trials, to ensure rapid and consistent research
- Similar endpoints across trials, to facilitate comparison of trial results
- Access to data that allowed evaluation of those endpoints

Q: If the price is very high, doesn't that mean it fails to meet "practical application" in the statute?

- NIH shares concerns about high drug prices and the burden they place on patients and their families, particularly the uninsured and the underinsured. NIH and HHS are pursuing a whole of government approach informed by public input to develop a framework for implementation of the march-in provision. This framework will clearly articulate the guiding criteria and processes for making determinations, including where pricing is a factor and how "practical application" is assessed in these determinations.
- Practical Application, as defined in the statute refers to the manufacturer in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.
 - *Criteria 1.* Action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

Q: Has a march-in petition ever been granted by NIH?

- To date, no federal agency has exercised its march-in rights. NIH has considered the use of march-in on several occasions. For example, in the case of CellPro, two competing companies were in a conflict over the right to advance a cell therapy, and there was a government-funded patent involved in that dispute. NIH worked with the relevant parties to reach an agreement that addressed the specific issue raised. And in the case of Fabrazyme, a manufacturer experienced critical difficulties and was unable to produce enough drug to supply patients with full doses of a product to treat a rare disease. NIH and FDA worked with the company until the matter was resolved. In both cases, NIH was able to work with the company to resolve the issue, and march-in was ultimately not needed.

Q: Has NIH received any prior march-in petitions for Xtandi?

- Similar petitions were submitted to NIH and the Army in 2016, requesting the use of march-in for Xtandi based on price. NIH and the Army each declined to exercise march-in authority as Xtandi was found to be widely available to the public in the marketplace.

Q: What did NIH fund in the development of Xtandi?

- NIH and the U.S. Army are cited as the sources of funding in three inventions utilized by Astellas Pharma, Inc. for manufacturing Xtandi (enzalutamide). This NIH funding (NIH Grant 5P50CA092131) supported University of California researchers in their discovery

of a new set of chemical compounds and their potential use in treating hormone refractory prostate cancer. These patents are under a license from the University of California, the patent owner.

Q: Why did it take over 12 months for NIH to come to this decision?

- NIH thoroughly reviewed the petition in a manner consistent with the policy and objectives of the Bayh-Dole Act, including an assessment of the relevant intellectual property and applicability of the four statutory criteria. This required time and careful consideration. During this time, NIH and HHS also launched a whole of government approach to develop a framework for implementation of the Bayh-Dole march-in provision.

Maternal Health Initiative

(Dollars in Millions)

Agency	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
AHRQ	--	7	+7
CDC	97	148	+51
HRSA	157	276	+119
IHS	7	10	+3
NIH ¹	30	30	--
Total	291	471	+180

^{1/} Does not include costs NIH would assume as one-time for Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone initiative.

TALKING POINTS:

- The FY 2024 budget includes \$471 million to continue HHS's longstanding efforts to **reduce maternal mortality and morbidity** rates; expand maternal health initiatives in rural communities; implement implicit bias training for healthcare providers; create pregnancy medical home demonstration projects; and address the highest rates of perinatal health disparities, including by supporting the perinatal health workforce.
- The U.S. has the **highest maternal mortality rate** among developed nations, with a higher proportion affecting Black and American Indian/Alaska Native women. HHS is working to **end these race-based disparities and address adverse maternal health outcomes** by supporting programs that address implicit biases, investing in innovative strategies to achieve equitable maternal care, establishing a diverse workforce, and ensuring federal funded activities focus on equal treatment, inclusion, and accessibility.
- HHS's maternal health initiatives **addresses this significant public health problem**. Investments focus on four strategic goals: 1) healthy outcomes for all woman of reproductive age, 2) healthy pregnancies and births, 3) optimizing postpartum health; and 4) improving data and bolstering research.

QUESTIONS:

Q: What investments have HHS made in the last fiscal year to address the nation's overall maternal health?

- HHS approved the extension of Medicaid and Children's Health Insurance Program (CHIP) coverage for 12 months after pregnancy. An estimated 333,000 Americans annually in 23 states and D.C. are now eligible for 12 months of postpartum coverage. If all states adopted this option, as many as 720,000 people across the United States annually would be guaranteed Medicaid and CHIP coverage for 12 months after pregnancy.

- HHS also invested investing \$8.5 million in initiatives designed to reduce pregnancy-related deaths and complications that disproportionately impact minority populations and those living in rural areas.
- HHS also awarded \$337 million to 56 states, territories, and nonprofit organizations through its Maternal, Infant, and Early Childhood Home Visiting Program to support communities and provide voluntary, evidence-based home visiting services to women during pregnancy, and to parents with young children up to kindergarten entry.

Medicare Coverage of Innovative Technology (MCIT) and Transitional Coverage for Emerging Technologies (TCET)

TALKING POINTS:

- HHS is committed to making sure people with Medicare are able to benefit from innovative, emerging technologies.
- HHS, through CMS, remains committed to establishing an expedited Medicare coverage pathway that achieves timely and predictable coverage of medical devices while at the same time ensuring that coverage is based on scientifically sound clinical evidence.
- HHS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections.

If asked about FDA/CMS authorities:

- The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) have different legal authorities to use when considering product authorization and coverage, respectively.
- The FDA makes marketing authorization decisions based on whether a product's safety and effectiveness while CMS makes coverage decisions based on something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- These two processes are separate and run independently by the two agencies.

QUESTIONS:

Q: Why did CMS repeal the January 2021 Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (R&N) final rule?

- The January 2021 final rule established a coverage commitment for breakthrough devices without requiring demonstration of a health benefit in the Medicare population.
- Additionally, stakeholders were concerned that a codified definition of reasonable and necessary would remove existing flexibility and potentially impact the ability for CMS to ensure equitable health care access for all people with Medicare.
- We believe it is important to solicit additional feedback on this topic. We look forward to continuing to engage with a wide number of stakeholders as we determine appropriate next steps that are in the best interest of people with Medicare and the program overall.

Q: Didn't CMS stifle innovation and limit access to new technologies by repealing the January 2021 MCIT/R&N final rule? Why can't Medicare just cover what the FDA approves?

- The repeal of the January 2021 MCIT/R&N final rule does not mean an item or service is not covered. Devices may still be covered through claim-by-claim determinations, one or

more local coverage determinations, or a national coverage determination. The standard for Medicare coverage is not synonymous with the standards for FDA marketing authorization of devices, which are not specific to the Medicare population.

- While the FDA generally reviews a device to ensure it meets the applicable safety and effectiveness standard, there is often limited evidence regarding whether the device is clinically beneficial to Medicare patients.
- Evidence on whether or not a device is clinically beneficial to Medicare patients is a key factor in determining national coverage under Medicare.

Q: What has CMS done since the January 2021 MCIT/R&N final rule was repealed? Why is it taking so long for CMS to release the proposed TCET rule providing for a new expedited coverage pathway?

- CMS remains committed to establishing an expedited Medicare coverage pathway that achieves timely and predictable coverage of medical devices while at the same time ensuring that coverage is based on scientifically sound clinical evidence.
- CMS continues to work closely with patient groups, medical professionals and societies, medical device manufacturers, other federal agencies (including the FDA), and others involved in developing innovative medical devices as it moves policy forward.

MA Prior Authorization Rules

TALKING POINTS:

- In December 2022, CMS issued the Advancing Interoperability and Improving Prior Authorization Processes proposed rule that would modernize the health care system by requiring certain payers—including Medicare Advantage organizations—to implement an electronic prior authorization process, shorten the time frames for certain payers to respond to prior authorization requests, and establish policies to make the prior authorization process more efficient and transparent.
- The proposed rule would address challenges with the prior authorization process faced by providers and patients.

QUESTIONS:

QA regarding support for Improving Seniors' Timely Access to Care Act (or generalized for other prior auth legislation)

- In December 2022, CMS issued proposed rules that would streamline prior authorization processes and improve prior authorization in Medicare Advantage to help Medicare Advantage enrollees have timely access to medically necessary care.
- We are grateful for your leadership on this important issue, including your work on the Improving Seniors' Timely Access to Care Act, and look forward to continuing to work with you and with Congress to make the prior authorization process more efficient and transparent in Medicare Advantage. HHS always appreciates the opportunity to provide technical assistance to Congress on important health care issues.

Medicaid Disproportionate Share Hospital (DSH) Proposed Rule

Talking Points

- In February 2023, CMS issued a proposed rule that would implement statutory changes made by the Consolidated Appropriations Act of 2021 to update the methodology for the calculation of the hospital-specific DSH limit.
 - The law modified the calculation of the Medicaid portion of the hospital-specific DSH limit to include only costs and payments for services furnished to beneficiaries for whom Medicaid is the primary payer for such services. Accordingly, the limit excludes costs and payments for services provided to Medicaid beneficiaries with other sources of coverage, including Medicare and commercial insurance.
- Additionally, the proposed rule would enhance administrative efficiency by making technical changes and clarifications to the DSH program.
- CMS is seeking public feedback on this proposal and will closely review the comments they receive as they move forward with the decision-making process.

Medicaid Health Taxes Guidance

TALKING POINTS:

- In February 2023, CMS issued an informational bulletin reiterating federal requirements concerning health care-related taxes and hold harmless arrangements involving the redistribution of Medicaid payments.
- HHS recognizes that health care-related taxes often finance critical programs that pay for care provided to Medicaid beneficiaries and shore up the health care safety net.
- HHS will continue to approve permissible health care-related taxes that meet federal requirements and remains committed to working with states.

Medicare HI Trust Fund

TALKING POINTS:

- The FY 2024 legislative proposed law package strengthens the Medicare Trust Fund for a generation, without cutting benefits.
- The President's budget puts the Medicare Trust Fund in the strongest position it's been in for over two decades.¹
- We achieve this by:
 - Directing all revenues from the net investment income tax, including tax code reforms that ensure high-income earners pay their fair share into the Medicare Hospital Insurance (HI) Trust Fund.
 - Crediting savings from prescription drug reforms to the HI Trust Fund.

QUESTIONS:

Q: How much of this plan is just general revenue transfers/gimmicks?

- This plan strengthens Medicare by ensuring that revenues going into the HI Trust Fund are sufficient to cover benefits. We achieve that by asking high-income people to pay a little more, achieving savings to Medicare from lowering the cost of drugs, without cutting benefits, and putting revenue that should have always gone to Medicare back where it belongs. Nothing about this proposal is a gimmick.
- The President fundamentally disagrees with those who believe that a conversation about Medicare should be a conversation about cutting benefits to seniors. His Budget shows that we can improve solvency while reducing seniors' costs – unless Congress takes revenues and prescription drug reforms off the table.
- *If pressed on general revenue transfers specifically:* The revenue from the Net Investment Income Tax was always intended to help strengthen Medicare. Fulfilling that purpose is both appropriate and important. Moreover, the large majority of the savings in this proposal come from new revenues and new prescription drug savings.

Q: Does your Budget double count the Medicare solvency provisions?

- The Budget appropriately and transparently accounts for the impact on both the unified Budget and the Trust Funds, in exactly the way that the Congressional Budget Office and all other scorekeepers do.

Q: Are the tax proposals consistent with the President's \$400,000 pledge?

- Yes. Nothing in the President's Budget raises taxes on people making less than \$400,000.

¹ The [2002 Medicare Trustees Report](#) projected Medicare solvency extension of 28 years.

Q: Is this an opening bid for a real negotiation with Republicans over Medicare solvency as part of debt limit discussions?

- First, let me reiterate the President's stance on the debt limit: the full faith and credit of the United States is not up for negotiation, and Congress needs to do its job and increase the debt limit without conditions.
- The President is including a plan to strengthen Medicare in his Budget because it's part of his vision for the nation's economic and fiscal future.
- He welcomes a conversation with congressional Republicans about their competing vision, and that's why he's urged them to put forward their own budget, which is a necessary step to having that conversation.
- But I'd also note that the President has been clear about some things he won't agree to, including cutting Medicare benefits or taking away people's health care.
- The President looks forward to working with Congress to continue to strengthen Medicare's finances and reduce the cost of drugs for seniors.

Q: When was the last time a President proposed strengthening the Trust Fund for over 25 years?

- The FY 2000 President's budget proposed general fund transfers to support Medicare for over 25 years. A few years later, the Medicare actuaries projected 28 years of Medicare solvency under current law.

Medicaid - Unwinding

TALKING POINTS:

- HHS is working with partners across HHS and the entire federal government to help reach communities that may be impacted by Medicaid redeterminations to help them **stay covered**.
- Over the past year, HHS divisions have taken over **100 actions** to support outreach on Medicaid redeterminations, including webinars, Dear Colleague Letters (DCLs), technical assistance, social media efforts, e-newsletters, and blog spots. This includes a letter from a year ago, May 2022, to Governors explaining CMS guidance on unwinding.
 - Some examples of that outreach include:
 - **ACF** sent Dear Colleague Letter to all grantees across all their Programs (Head Start, TANF, Child Welfare, etc.) laying out what they can to support our efforts.
 - **IHS** hosted a webinar with Indian Health Service, Tribal, and Urban Indian Health programs focused on providing guidance on helping people overcome administrative barriers to maintain coverage.
 - **HRSA** shared messaging via the Primary Health Care Digest—reaching 48,000 recipients—, a weekly electronic newsletter for Health Center Program grantees, look-alikes, training and technical assistance partners, and other stakeholders, encouraging these organizations to communicate with patients about coverage options.

QUESTIONS:

Q: What barriers have you seen that will prevent people from easily enrolling in their state? For example, I heard that South Carolina has paper-only re-enrollment and doesn't allow any electronic re-enrollment.

- CMS is working closely with states on their unwinding plans, including assessing state compliance with federal Medicaid redetermination requirements and, where necessary, developing mitigation strategies to address gaps/deficiencies.

Q: What are you doing to ensure that individuals are able to retain access to health coverage during unwinding?

- HHS has been collaborating closely with state agencies, other federal agencies, and stakeholders to plan and prepare for the end of the continuous enrollment condition through regular workgroups, all-state calls, and individualized technical assistance. These efforts are aimed at ensuring eligible enrollees retain coverage by renewing their Medicaid or CHIP coverage, and enrollees eligible for other sources of coverage smoothly transition.

- CMS has announced a Marketplace Special Enrollment Period (SEP) for qualified individuals and their families who lose Medicaid or CHIP coverage due to the end of the continuous enrollment condition. In October 2022, CMS also issued final rulemaking to establish a Medicare SEP to Coordinate with Termination of Medicaid Coverage, which allows individuals who have missed a Medicare enrollment period to enroll in Medicare after termination of Medicaid eligibility.

Q: How many people do you expect to lose Medicaid coverage this Spring and Summer?

- States will have up to 12 months to initiate, and 14 months to complete, a renewal for all individuals enrolled in Medicaid. CMS is working closely with states on their unwinding plans, and CMS will be monitoring monthly data about activities related to eligibility determinations and redeterminations conducted during the unwinding period, including data related to terminations of coverage and transitions to other sources of coverage. CMS will be reviewing this data, state activity, and other information to ensure all states comply with federal requirements related to eligibility redeterminations and renewals, and is committed to providing additional information once available.
 - **IF PRESSED:** According to estimates from the Office of the Assistant Secretary for Planning and Evaluation, 15 million people could be disenrolled from Medicaid during this time period, and 8 million of those individuals will be eligible for other health coverage.

Q: HHS ASPE projects that 15 million individuals will lose Medicaid coverage, and other studies estimate 16 million. What is the difference between these projections and the projections in the Budget?

- CMS Actuaries project that 16.9 million individuals will lose Medicaid coverage in FY 2024 as a result of the ending continuous enrollment condition, and 19.5 million will lose coverage over the course of the unwinding period. Some reasons for the differences between the actuary projections and other studies include:
 - CMS actuaries follow a timeframe of the fiscal year for purposes of the President's Budget
 - CMS actuaries do not account for churning, beneficiaries going on and off of coverage, in their projections they develop for budget purposes
 - CMS actuaries uses data from the Transformed Medicaid Statistical Information System (T-MSIS). Other studies may use different data sources with different metrics that could lead to variances in projections.

Q: Will the special enrollment period be available in all states, even the ones that don't rely on HealthCare.gov for their Marketplace?

- State-Based Marketplaces that operate their own eligibility and enrollment platforms can offer this SEP for their populations, and HHS encourages them to do so.

Q: Why aren't you requiring all states to offer the special enrollment period?

- State-Based Marketplaces that operate their own eligibility and enrollment platforms must determine whether to offer this SEP for their populations, and HHS encourages them to do so.

Q: Will Medicaid still be required to cover COVID-19 vaccines, testing, and treatment?

- If the COVID-19 PHE ends as expected on May 11, 2023, this COVID-19-specific coverage requirement will end on September 30, 2024. Under the American Rescue Plan Act of 2021 (ARP), states must provide COVID-19 vaccinations, testing, and treatments under Medicaid and CHIP without cost sharing for through the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE.
- Even after the ARP provision expires, most people enrolled in Medicaid or CHIP will be guaranteed coverage of all approved vaccines, including COVID-19 vaccines, recommended by the Advisory Committee on Immunization Practices. That is because the Inflation Reduction Act closes gaps in vaccine coverage for adults in Medicaid and CHIP effective October 1, 2023. Medicaid and CHIP coverage of COVID-19 treatments and testing may vary by state.

Medicare Advantage

TALKING POINTS:

- Our vision for Medicare is for all seniors and people with disabilities to receive equitable, high quality, and person-centered care that is affordable and sustainable. This applies to beneficiaries in traditional Medicare and in Medicare Advantage.
- We recognize that Medicare Advantage is important for many beneficiaries. That's why we issued a Request for Information (RFI) last year seeking input on how to improve the MA program.
- Using this feedback, across multiple rules and the Advance Notice, we have proposed policies to strengthen beneficiary protections and enhance the MA program, including improvements that enhance payment accuracy.

QUESTIONS:

Medicare Advantage Advance Notice

Q: Is the MA Advance Notice actually a cut to Medicare and MA plan payments?

- Any claim that this Administration is cutting Medicare is categorically false.
- This Administration has proposed a roughly \$4 billion increase in MA payments for next year.

Q: What will the impact be on dually-eligible beneficiaries, lower-income enrollees, and racial or ethnic minorities?

- Bottom line, we are not proposing any policies that harm vulnerable beneficiaries.
- CMS is proposing essential updates to the risk adjustment model, including updates to reflect more recent cost and utilization data and to incorporate ICD-10 codes. These updates improve payment accuracy.
- We will continue to pay much more for someone who is dually eligible than someone who isn't even when they have the same diagnoses, and Federal law protects most dually eligible individuals from any cost sharing for Medicare services.
- The Medicare Advantage market is strong, and nothing in the Administration's proposed policies will change that.

Q: Will MA plans reduce the benefits they offer or increase premiums because of the Advance Notice?

- To be clear, on average, the Advance Notice would provide a payment increase for MA plans of 1.03%, or more than \$4 billion, next year.
- Also, all core Medicare benefits – such as hospital care and physician visits – are guaranteed in Medicare Advantage like they are in Traditional Medicare. These changes do not impact that requirement.

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- Looking at the past is helpful here. There have been years when the MA increase was smaller than what is proposed for 2024. We did not see premiums increase over those years. Instead, premiums remained relatively stable.
- MA is a highly competitive market where plans often compete for enrollees by keeping premiums down. In this competitive environment, we expect premiums to remain low.

Mental Health Parity

TALKING POINTS:

- The President's FY 2024 Budget includes numerous proposals to improve patient protections and strengthen enforcement of mental health parity requirements, including:
 - o Funding to states for parity enforcement;
 - o Eliminating Medicare's 190-day lifetime limit on psychiatric hospital services;
 - o Subjecting more plans – including Medicare Advantage plans – to parity laws; and
 - o Authorizing the Secretaries of HHS, Labor, and Treasury to regulate behavioral health network adequacy, and to issue regulations on a standard for parity in payment rates.
- The budget includes a proposal requiring Medicare and private insurance to cover up to three behavioral health visits per year with no cost-sharing. Eliminating cost-sharing for individuals removes potential financial barriers to treatment and gives more patients access to the care they need.
- The budget also includes a proposal to allow Medicare to identify and designate additional professionals to provide behavioral health care services, expanding access particularly in rural and underserved areas.

QUESTIONS:

Q: What does HHS do to enforce mental health parity requirements? Do you audit plans?

- HHS has primary enforcement authority over issuers in states that do not have authority to enforce or fail to substantially enforce the Mental Health Parity and Additional Equity Act (MHPAEA) (referred to as direct enforcement states) and non-Federal governmental health plans in all states.
- CMS is tasked with carrying out HHS's enforcement responsibilities.
- While CMS has some enforcement authority, states are the primary enforcers of mental health parity for health insurance issuers. The President's FY 2024 Budget includes a proposal that would grant states an additional \$125 million in funding for enforcement activities.

Q: Congress just added marriage and family therapist services to the Medicare statute, why are additional changes needed to Medicare?

- There are current statutory limits on the types of practitioners, and the scope of services, that are eligible for Medicare payment and these limits restrict access to behavioral health services.
- The Consolidated Appropriations Act of 2023 added coverage of marriage and family therapist services and mental health counselor services under Part B of the Medicare program starting January 1, 2024.
- However, other providers including peer support workers and certified addiction counselors are still unable to bill Medicare directly.
- The Budget proposes to allow Medicare to identify and designate additional professionals who can enroll in Medicare and be paid when furnishing behavioral health services within their

applicable state licensure or scope of practice that would otherwise be covered when furnished by a physician.

- The proposal also:
 - o Removes limits on the scope of services for which Clinical Social Workers can be paid by Medicare.
 - o Establishes a Medicare benefit category for these professionals that authorizes direct billing and payment under Medicare for these practitioners;
 - o Removes limits on the scope of services for which they can be paid by Medicare;
 - o Allows these practitioners to bill Medicare directly for their mental health services for covered Part A qualifying Skilled Nursing Facility stays;
 - o Establishes Medicare payment under Part B for services provided under an Assertive Community Treatment delivery system which provides treatment for the severe functional impairments associated with serious mental illness;
 - o Allows payment to Rural Health Clinics and Federally Qualified Health Centers for these additional behavioral health professionals providing mental health services; and
 - o Enables Medicare coverage of evidence-based digital applications and platforms that facilitate the delivery of mental health services.

Mental Health – Youth

TALKING POINTS:

- Children and young people in this country are facing an unprecedented behavioral health crisis
- Diagnosis of anxiety, depression, and other mental health conditions, as well as the rate of youth overdose deaths continue to rise at alarming rates.
- Improving mental health and wellness for everyone -- particularly for children and young people—and addressing the challenges that have been exacerbated by the COVID-19 pandemic is a top priority for HHS.

QUESTIONS:

Q: How has the COVID-19 pandemic and mask wearing impacted children's mental health and what is HHS doing about it?

- Data show that for across a broad range of social, emotional, and cognitive outcomes, allowing kids to attend school in person is incredibly important.
- Accordingly, the Biden Administration has prioritized in-person schooling in its COVID response plan.
- HHS is responding to the current crisis by developing and expanding grant programs that address the mental health needs of our children and youth, including school-based programs and community-based trauma-informed services for children and youth, and their families that meet children and families where they are.

Q: A few months ago, HHS/SAMHSA released the results of its annual National Survey on Drug Use and Health. In 2021 amount people 12 and older, 61.2 million people, 21.9 percent of the US population, used illicit drugs this past year. 3.7 million, 14.1 percent of 12- to 17-year-olds have used illicit drug. These are children and substance use among America's kids only seem be increasing. Why should we continue providing SAMHSA additional dollars when it is clear what you are doing is not making a positive impact?

- There is no question that more needs to be done, and with support from Congress we are taking action, expanding grant programs that address the mental health needs of our children and youth, including school-based programs and community-based trauma-informed services for children and youth, and their families that meet children and families where they are.

If pressed on the specifics of the data and year-over-year increase:

- To clarify, estimates from the 2021 National Survey on Drug Use and Health should not be compared with estimates from previous years because the COVID-19 pandemic necessitated methodological changes to the data collection process.

- HHS is committed to providing access to prevention and treatment services to everyone, include youth and young adults, and a commitment to data and evidence is one of SAMHSA's four core principles.
- The National Survey on Drug Use and Health is a vital data tool that supports SAMHSA's mission and aligns with SAMHSA's vision to guide stakeholders in developing policies and programs to help people in the United States who have, are affected by, or are at risk for mental health or substance use conditions receive care, thrive, and achieve wellbeing.

Q: Please give an example of how HHS agencies are coordinating to address youth mental health and substance use disorder conditions?

- When I was confirmed, I immediately established the Behavioral Health Coordinating Council (BHCC)—all HHS agencies participate and lead committees across five key areas: data and evaluation, youth, crisis and suicide, overdose prevention, and integration. Committees all consider equity and workforce as part of their charge.
- SAMHSA and CMS lead our BHCC youth group together. And they also work together through the Interdepartmental Serious Mental Illness Coordinating Committee, which was established to make recommendations for actions that federal departments can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance, has parity implementation as a goal.

Mifepristone

TALKING POINTS:

- [ON HOLD UNTIL DECISION]
- Holding Statement if Decision Comes out During Hearing:
 - “This is chilling news for America and will have dire consequences for women across the country. The Biden-Harris Administration is resolute in our commitment to protect access to abortion care – we are looking closely at the decision and are examining our options.”

QUESTIONS:

Q: Does HHS have any workarounds to this decision?

- [ON HOLD UNTIL DECISION]

Q: What do providers/patients do with existing mifepristone?

- [ON HOLD UNTIL DECISION]

Q: If you feel that this decision was made erroneously, why don't you just defy the ruling?

- [ON HOLD UNTIL DECISION]

Q: Are you going to issue a Public Health Emergency to increase access to reproductive health care?

- We have always said we would not take any option off the table that will help expand access to reproductive care.
- But, at this point in time, we do not believe that declaring a public health emergency would provide meaningful new resources in this fight.

Nonrecurring Expenses Fund

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Notification	525	650	125
Rescission	(650)	(350)	300

TALKING POINTS:

- HHS relies on modern information technology and safe and functional facilities to meet its mission to enhance the health and well-being of Americans.
- The Nonrecurring Expenses Fund enables HHS to address high-priority capital investments that simply do not get funded in the annual appropriations process.
- Every dollar rescinded from the fund comes at the expense of keeping departmental systems and facilities in good working order.
- Approximately two-thirds of HHS' NEF-eligible needs are not even proposed to Congress due to these rescissions and allocations.

QUESTIONS:

Q: How much of the NEF has funded Capital Expenditures?

- By statute all NEF investments must be capital expenditures necessary to operate the Department. Since its inception, HHS has obligated \$1.9 billion in facilities and \$2.7 billion in IT capital expenditures previously notified to Congress. HHS is currently in the process of spending the remaining \$1.3 billion in notified funds.

Nursing Homes - Staffing Ratios

TALKING POINTS:

- One of the key areas of focus in President Biden's nursing home quality initiative is nursing home staffing.
- The COVID-19 pandemic highlighted and exacerbated the long-standing staffing challenges experienced in many facilities, creating an urgent need to address this issue for the well-being of all individuals residing in our nation's federally certified nursing homes, and the workers who care for them.
- HHS has launched a multi-faceted approach aimed at determining the minimum level and type of staffing needed to enable safe and quality care in nursing homes. As part of this effort:
 - o CMS is currently in the process of conducting a mixed methods study
 - o CMS will release a proposal in spring 2023 for minimum staffing levels in nursing homes.

QUESTIONS:

Q: How has the nationwide health care workforce shortage impacted rural providers that are already struggling?

- We know that providers across the country are still facing challenges introduced or exacerbated by the COVID-19 pandemic, including workforce shortages, and these challenges can be particularly difficult for providers in rural areas.
- Health care should be accessible, no matter where you live, and the Biden-Harris Administration is dedicated to improving access to health care in rural communities and addressing the issues which contribute to health inequities impacting these communities.
- Fewer nurses are working in rural areas today than in the past. HHS is investing \$387 million an increase of \$190 million for Behavioral Health Workforce Development Programs, which will support the training of 18,000 behavioral health providers and seek to place these providers in rural and underserved areas.

Q: Will your nurse staffing proposal include an exception or other flexibilities for rural nursing homes?

- We are aware of the unique challenges facing rural nursing homes and we are taking those challenges into account as we develop the proposal. We look forward to robust comment from the rural community on the proposal when it is released.

Q: The health care workforce shortage is reaching a crisis, yet the Administration still refuses to let healthy, qualified professionals work unless they've received an experimental vaccine that doesn't even prevent COVID-19. Now that the Public Health

Emergency is coming to an end, don't you think it's time to get rid of the vaccine mandate as well?

- We know that the COVID-19 vaccine saves lives, and the Biden-Harris Administration has made it a priority to continually work to reach, vaccinate, and protect our most vulnerable communities across the country.
- Hospitalizations and deaths from COVID-19 currently remain relatively low nationwide. This is a testament to the tools and protections put in place by this Administration, including efforts to educate consumers and expand access to the vaccine.
- HHS is committed to taking critical steps to protect vulnerable individuals and ensure America's health care facilities are prepared to respond to public health emergencies.

Ohio Train Derailment

TALKING POINTS:

- HHS stands with the people and communities impacted back the train derailment in Norfolk Southern. Multiple parts of HHS are part of the federal response.
- In February, CDC/ATSDR sent a team of 23 staff to conduct an Assessment of Chemical Exposures (ACE) investigation, including door-to-door recruitment of affected residents.
- As of March 7, 2023, over 420 residents and 190 first responders have participated in the ACE survey.
 - The investigation is providing information to inform the states' public health response, assess the need to modify emergency response procedures, focus outreach efforts, and identify groups of exposed people that may need additional follow-up.
- The Health Resources and Services Administration (HRSA) has provided an emergency grant to the Community Action Agency of Columbiana County (CAAC). HRSA approved, \$250,000 in emergency funding. This funding will support key response activities, including direct health care services, patient screenings, and outreach and enrollment.
- HHS will continue to support the community throughout the next stages of the response whether that's through reviewing environmental sampling data to assess public health impact or to provide mental health support, we stand ready to assist.

QUESTIONS:

Q: Some residents and experts have stated a need for testing to measure the level of chemicals the residents and responders to the East Palestine incident were exposed to. Why hasn't CDC/ATSDR offered biomonitoring or other testing to residents?

- I understand that many residents and responders have concerns regarding the longer-term health outcomes resulting from the train derailment. HHS is committed to supporting the residents of East Palestine and the surrounding communities to address their concerns, including answering their questions about how testing may help them protect their health.
- At this time, CDC and ATSDR are not recommending specialized testing for the levels of chemicals in people's bodies, as tests for the chemicals involved in this event do not usually provide information to help doctors manage health problems or disease.
- We are supporting state efforts to connect concerned residents with medical providers to ensure they have access to follow-up care in the long-term to address any individual health issues that may arise.
- CDC and ATSDR are also working with partners to provide information to health care providers about additional steps they can take in consultation with their patients, including other routine blood and urine tests that they can take to protect their patients' health.

Q: When will you have ACE results? Will there be one report? Who will release the report/findings and how long will this take?

- The resident and responder surveys for the Assessment of Chemical Exposures, or ACE, investigation will be open through the end of the month, and data analysis is ongoing. Over the next several months, CDC and ATSDR will work together with the health departments to analyze data and share results.
- These results will provide information about appropriate next steps to address potential health impacts of exposures.
- This is a collaborative, iterative process and CDC/ATSDR will continue to work closely with the health departments as the analyses are completed and results are shared.

Q: Does the CDC recommend that we study these people over time to learn about the health effects?

- The health of the residents and the community overall is very important to us. I know that community members are concerned about their health and understand how unsettling it can be not to know what these exposures mean.
- We hope to learn more from the ACE survey in the community and among responders to give us more information to address the health concerns of the residents.
- We will analyze the data with our colleagues from the Ohio and Pennsylvania health departments and come up with a plan for next steps. This may include long-term health monitoring, additional epidemiologic support, or suggest research studies to fill knowledge gaps.

Q: How does ATSDR produce their screening levels for exposures (also called comparison values). How are these values used and why are these values different than the ones the EPA and health departments are using?

- ATSDR has been on the ground supporting the EPA and local officials in their response to the derailment for over a month. At the request of the EPA and state health departments, ATSDR provided comparison values to the EPA and state health departments for consideration in their risk management process.
- We defer to EPA and the state health departments for more information on how these comparison values are used in the risk management process.
- Determining the threshold for unsafe levels of chemical exposure is a complex process given there are many site-specific factors that need to be considered. ATSDR derives non-regulatory comparison values as screening values to help public health professionals determine which exposures may need further evaluation. ATSDR uses the lowest comparison value available to protect public health for a specific incident.

- Concentrations below these values are unlikely to cause harmful health effects. Exposures above these values do not necessarily mean that harmful effects will occur but serve as a signal for public health professionals to look more closely.

Older Americans Act

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Protection of Vulnerable Older Adults	96	144	+49
Health and Independence for Older Adults	1,587	1,939	+352
Caregiver Services	259	311	+49
Total Program Level	2,650	3,142	+493

TALKING POINTS:

- At some point in our lives, nearly all of us will need assistance with things like transportation, personal care, and managing finances, or provide assistance to someone else we care about. Strengthening and supporting the caregiving infrastructure is a top priority for this Department.
- ACL's budget request includes an increase of nearly \$66 million to support:
 - a range of services to support family caregivers including respite care,
 - efforts to implement recommendations from the National Strategy to Support Family Caregivers, and
 - demonstration grants and a technical assistance center to expand and stabilize the direct care workforce.
- The demand for services provided through the ACL's programs has risen sharply in recent years and continues to grow. Expanding access to these direct services is a priority.

QUESTIONS:

Q: Falls among older adults result in \$50 billion in medical costs annually – \$38B in Medicare and Medicaid; and \$12B in private insurance or out-of-pocket expenditures. What are you proposing to improve this situation?

- First, I wanted to thank Congress for your support of HHS falls prevention work. In particular, the \$5 million that was appropriated in FY 2023 for the Administration for Community Living's Research, Demonstration and Evaluation Center. Those funds are supporting continued research in the causes and associated illnesses that can lead to falls as well as interventions effective in preventing falls.
- As part of ACL's investment in direct services, we are requesting an additional \$2 million within our promoting healthy aging efforts to expand the successful evidence-

based falls prevention program in the community and educate more older Americans about ways to reduce their falls risk.

Q: You have indicated that direct services for older adults and people with disabilities are a priority and nutrition services in particular. Why are you proposing to cut the Nutrition Services Incentive Program by \$48 million?

- I agree, funding to meet nutrition needs – whether at group dining sites like senior centers or through home-delivered meals – are critical to enabling seniors to remain in their communities and to age in place. The Nutrition Services Incentive Program is a secondary source of funding for the nutrition services.
- We have requested an overall increase to these programs through their primary funding, which comes to \$217.6 million over the FY 2023 budget. We believe increasing primary funding will have the most direct impact on addressing the nutrition needs of seniors.

Q: What does this budget do to address elder abuse and neglect?

- Abuse and neglect rob people of their fundamental human rights and erode their opportunity to participate as members of the community. We are in a national crisis – abuse of older adults increased nearly 84 percent during COVID.
- I thank Congress for providing the first federal funding for APS formula grants in FY 2021 and I am so pleased that ACL received ongoing funding to support Adult Protective Services in FY 2023.
- Our request for FY 2024 is to get to a basic level of funding to continue to protect older adults and adults with disabilities from abuse and neglect.

Organ Transplantation

(Dollars in Millions)

	FY 2023	FY 2024	
	Enacted	President's Budget	+/- FY 2023 Enacted
Organ Transplantation	31,049	67,049	+36,000

TALKING POINTS:

- Today, HRSA announced a new Modernization initiative to strengthen accountability and transparency in the Organ Procurement and Transplantation Network (OPTN). It is focused on three things:
 - 1) Data Transparency. We will be posting data dashboards for the public so patients, families, and providers has access to the data we have. e are committed to increasing the number of registered organ donors and initiatives to remove financial barriers to living organ donation and to ensure that donor allocation is done in a transparent and equitable manner.
 - 2) Competition: OPTN has had same contractor for 40 years and HRSA is announcing their intent to issue contract solicitations for multiple awards to manage the OPTN later this year.
 - 3) Modernization: In order to best serve patients, need to modernize the IT system with industry standards.
- We want to work with Congress to continue our efforts to improve organ transplantation. The President's Budget includes a proposal for the resources and authorities needed to oversee the operational activities, performance, and accountability of the OPTN.

QUESTIONS:

Q: How is HHS providing oversight to ensure accountability and equity of the Organ Transplantation and Procurement Network system?

- The Budget provides an additional \$37 million to increase accessibility, transparency, and equitable distribution of organs through modernization of the Organ Procurement and Transplantation Network.
- Specifically, the request will support efforts to:
 - strengthen policy, governance, and technology to drive improvements in IT system performance, health equity, patient outcomes and patient safety
 - launch implementation of the design features needed to improve system processes, patient experience, and accountability

Oversight

TALKING POINTS:

- HHS is committed to working in good faith to address congressional oversight requests in a timely manner.
- Already this Congress, HHS has made significant document productions in response to multiple committees' oversight inquiries, and I know we are actively working to continue addressing Congress's oversight requests.
- We look forward to working together and continuing our productive relationships with Congress.

QUESTIONS:

Q: Will you provide complete responses to my oversight requests by the deadline requested?

- We are committed to engaging in good-faith negotiations to meet the informational needs of Congress while protecting the institutional interests of the executive branch.
- We will continue to engage in this process to address congressional oversight requests, like we always have.
- *If pressed on commitments:* I know our staff is working hard to address the significant number of oversight requests that we have received this Congress. We look forward to continuing those discussions.

Q: Is it your policy that Committee Chairs must send new oversight letters this Congress to get answers to letters we sent in the last Congress?

- It is my understanding that, when a new Congress begins, there is a long-standing practice across Departments for oversight requests to be sent by the new Chairs, once they have been selected.
- This helps ensure we are prioritizing oversight requests from current committee Chairs.
- The Department welcomes current Chairs to send oversight letters identifying their priorities for this Congress and stands ready to work in good faith to address these requests.

Pandemic Preparedness

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA	153.113	181.880	+28.767
CDC ¹	1,654.300	2,037.400	+383.100
NIH ²	2,943.000	2,944.000	+1.000
ACF	1.864	8.000	+6.136
ASPR ³	3,629.677	4,271.913	+642.236
PHSSEF ³	115.992	278.318	+162.326
Pandemic Preparedness Initiative	--	20,000	+20,000
Total Program Level	8,497.946	29,721.511	+21,223.565

1/ FY 2023 totals are comparably adjusted to reflect funds for HHS Protect within CDC's Center for Preparedness and Response. The FY 2023 enacted located HHS Protect Funding within PHSSEF, but the program is implemented by CDC.

2/ NIH estimates for FY 2023 and FY 2024 align to the NIH Biodefense category.

3/ The Public Health and Social Services Fund previously contained the annual appropriation for the Administration for Strategic Preparedness and Response (ASPR). The FY 2024 budget requests funding for ASPR in a separate, new appropriation account. This table is comparably adjusted to break out ASPR from the PHSSEF.

TALKING POINTS:

- Strengthening our nation's preparedness for public health threats of all sources is a national security imperative and a top priority for this Administration.
 - HHS has had to overcome real administrative challenges and a patchwork of authorities and flexibilities while responding to the once-in-a-century COVID-19 pandemic and other recent emergencies, including the infant formula shortage and Hurricanes Ian and Fiona.
- This work is **mission-critical** for HHS, we must better respond to future outbreaks, strengthen domestic production capabilities and anticipate and prevent their worst public health and economic harms.
- We propose a suite of funding and legislative proposals to strengthen capabilities across early threat detection, supplies and medical countermeasures, workforce, recovery, and core infrastructure and capabilities.
- This includes discretionary investments and \$20 billion in mandatory funding requested across HHS public health agencies to prepare for pandemics and other biological threats. Together, these proposals will help bridge key gaps and barriers to enable a robust and timely response to future emergencies.
- I stand ready and eager to discuss the path forward with Congress.

QUESTIONS:

Q: Last Congress, we passed the PREVENT Pandemics Act, didn't that get HHS the authorities it needs to better respond to emerging public health threats?

- First, I want to thank Congress for working on bipartisan basis to support HHS work on pandemic prevention.
- PREVENTs took us one step forward, but the proposal in the FY2024 budget and Congress' work to reauthorize the Pandemic All-Hazards and Prevention Act (PAHPA) will provide enduring ability for the department to leverage the processes we know worked from COVID-19, like DOD's contracting authority for rapid research, and development and procurement of vaccines and medical countermeasures. HHS will be able to leverage to prepare and respond to future public health threats.

Q: Right now, the Centers for Disease Control and Prevention (CDC) do not have an explicit authorization. Do you think Congress should authorize the CDC and if so what should it look like?

- CDC launched Moving Forward to strengthen CDC by strategically building on lessons learned during the COVID-19 pandemic to break down silos, reduce bureaucracy, and improve accountability.
- This effort will be critical to deliver health information more clearly and quickly to policy makers and American. We're already seeing the benefits of this effort:
 - o CDC was the first in the world to produce data showing real-world effectiveness of the JYNNEOS vaccine for mpox.
 - o Two public-facing databases went live in April 2022 that provide public health practitioners and the public with critical data about non-fatal overdoses and overdose deaths to tailor interventions in their communities.
- As CDC makes the changes it can internally, we also need help from Congress through funding and new authority to fully deliver on its mission of protecting the health, safety, and security of Americans.

Q: Why is the Pandemic Preparedness Mandatory Proposal \$20 billion less? If this is mission critical why are you proposing less funding to achieve the same goals?

- The Administration remains committed to transforming the way we prepare for and respond to pandemic and other biological threats. That's why we are again asking Congress to enact bold legislation.
- The \$20 billion proposal in the FY 2024 budget is a targeted investment. While it cannot do everything, it will allow for significant progress toward meeting the Administration's preparedness goals, as outlined in the National Biodefense Strategy and Implementation Plan and American Pandemic Preparedness plan.

Q: U.S. intelligence assessments point to the possibility that SARS-CoV-2 originated from a leak at the Wuhan Institute of Virology (WIV). Did HHS/NIH fund work at WIV that resulted in the pandemic?

- NO. NIH has never approved any research that would make a coronavirus more dangerous to humans. The body of science reported—including the bat coronavirus

sequences published in the scientific literature—showed that the viruses studied at WIV under the NIH grant were evolutionarily quite distant from SARS-CoV-2 and could not have been the source of SARS-CoV-2.

- The origin of SARS-CoV-2 virus has not been identified, despite intensive efforts. It took 14 years for scientists to find a single bat population that contained all the necessary genetic components of SARS-CoV, the virus that caused the 2003 SARS epidemic. We still do not know the origins of the 2014 Ebola outbreak.
- HHS strongly supports efforts to identify the SARS-CoV-2 origin.

Q: What is HHS/NIH doing to ensure biosafety and biosecurity of research involving pandemic pathogens?

- HHS/NIH is committed to ensuring the safety and security of the work we support. The U.S. has a robust biosafety and biosecurity oversight system that is predicated on identifying and assessing benefits and risks, and appropriately mitigating risks at both the Federal and institutional levels. We periodically review, and as needed, update our oversight frameworks to help ensure our biosecurity oversight frameworks keep pace with rapid advances in science.
- In February 2022, HHS tasked the National Science Advisory Board for Biosecurity (NSABB), a federal advisory committee, with reviewing the scope and effectiveness of two major U.S. biosecurity policy frameworks governing research with enhanced potential pandemic pathogens and dual use research of concern.
- The NSABB's final report was delivered in March 2023. NSABB findings and recommendations will inform ongoing USG policy deliberations.

Q: Did the NSABB consider the origins of the SARS-CoV-2 pandemic and NIH's funding of research in China?

- No, investigating the pandemic's origin was not the role of the NSABB and many other investigative bodies have been tasked with this charge.

Q: Given the potential risks, why does HHS/NIH support research involving potential pandemic pathogens?

- Research involving potential pandemic pathogens can help us understand the fundamental nature of human-pathogen interactions, assess the pandemic potential of emerging infectious agents such as viruses, and inform public health and preparedness efforts, including surveillance and the development of vaccines and medical countermeasures.
- While such research is inherently risky and requires strict oversight, the risk of not doing this type of research and not being prepared for the next pandemic is also high.

Q: Why does HHS/NIH support pathogen research in foreign countries?

- HHS/NIH supports research to better understand the characteristics of animal viruses that have the potential to spill over to humans and cause widespread disease. We must collaborate with researchers in other countries where these viruses are prevalent because once a virus spreads to humans, it is not contained by geographical boundaries. Our support ensures that the information will be shared.
- This has helped us to assess the pandemic potential of emerging infectious pathogens, including coronaviruses that have caused SARS and MERS. This is our best path to inform the development of medical countermeasures such as vaccines. It would be irresponsible for us not to do this work.
- In fact, this body of work has helped make it possible for the U.S. government to move so quickly to get a COVID-19 vaccine in an unprecedented timeframe of just 11 months. Countless lives have been saved as a result.

Public Health Emergency - Uninsured Program

TALKING POINTS:

- The Biden-Harris Administration is committed to ensuring continued access to COVID-19 vaccines and treatments for all Americans.
- Congress established funding for the Uninsured Program to provide claims reimbursement to health care providers for during the COVID-19 pandemic testing, treatment and vaccinations administration for uninsured individuals.
- As of March 1, 2023, HHS has made **\$24.5 billion in claims reimbursement payments** to providers for testing, treatment, and vaccination of uninsured individuals. Including:
 - Over 11.3 billion claims for testing;
 - 5.8 billion claims for treatment; and
 - 1.6 billion claims for vaccine administration.
- HHS has processed and paid nearly all eligible claims submitted to the program by the deadlines. There are a small number of claims remaining requiring technical, administrative adjustments or program integrity review.
- Due to a lack of sufficient funding, in March 2022, HHS announced that the COVID-19 Uninsured Program would have to stop accepting claims. To date, no additional funding has been appropriated for the Uninsured Program.

QUESTIONS:

Q: How much has been spent on the Uninsured Program?

- As of March 1, 2023, HHS has made \$24.5 billion in claims reimbursement payments to providers for testing, treatment, and vaccination of uninsured individuals.

Q: How much is money is left in the Uninsured Program?

- On March 15, 2022, the White House announced that the COVID-19 Uninsured Program would have to stop accepting claims for testing and treatment on March 22, 2022, and stop accepting claims for vaccination administration on April 5, 2022, due to a lack of sufficient funding.
- To date, no additional funding has been appropriated for the Uninsured Program, and claims are no longer being accepted.

Q: Is HHS still processing claims in the Uninsured Program?

- HHS has processed and paid nearly all eligible claims submitted to the program by the deadlines. There are a small number of claims remaining requiring technical, administrative adjustments or program integrity review.

Q: How did HHS prevent fraud or abuse in the Uninsured Program?

- HHS implemented numerous program integrity and fraud prevention measures as part of the Uninsured Program. To participate in the Uninsured Program, providers were required to undergo multiple verification steps, including submitting their *National Provider Identifier* (NPI) and their Tax Identification Number for validation. Providers also were checked against several provider compliance and exclusion lists to assess whether they are in good standing.
- Specifically, HHS excludes providers who:
 - o Were excluded from participation in Medicare, Medicaid, or other Federal health care programs;
 - o Were on the List of Excluded Individuals/Entities from HHS's Office of the Inspector General; or
 - o Were terminated from participation in Medicare or precluded from receiving payment through Medicare Advantage or Medicare Part D; or
 - o Had their Medicare billing privileges revoked.
- Providers who are suspected to be or found to be out of compliance with the terms and conditions of the Uninsured Program can be subject to holds on reimbursements, post-payment reviews, termination from the program, recovery of funds, and referral to law enforcement as appropriate.

Public Health Emergency and Telehealth (not controlled substances)

TALKING POINTS:

- **PHE END BUDGET:**

- **Medicaid**

- In FY 2024, the federal government will spend an estimated \$556.2 billion on the Medicaid program, a decrease of \$51.5 billion below 2023. This decrease in spending is due to the end of the continuous enrollment condition in Medicaid on March 31, 2023.
 - CMS continues to work with states on their Medicaid and CHIP renewal plans and system readiness as the continuous enrollment condition comes to an end on March 1, 2023. CMS also focuses on continuity of coverage and streamlining transition to alternate forms of coverage for beneficiaries by launching two outreach and information campaigns targeted towards beneficiaries, and announcing a marketplace special enrollment period for individuals who lose Medicaid coverage during the unwinding period.

- **Private Insurance**

- The FY 2024 budget includes \$281 million for Marketplace consumer information and outreach and \$141 million for Navigators. This includes paid media and direct consumer enrollment assistance, which will support the transition of eligible Medicaid recipients to Marketplace coverage.

- **Discretionary**

- Digital Healthcare Research: +\$2 million above FY 2023 enacted, for a total of \$18 million for AHRQ's Digital Healthcare Research Program. Increases will be used to establish Centers of Excellence in Telehealth Implementation that will generate essential new evidence to understand telehealth's effect on access, equity, and quality and inform key policy decisions to maximize telehealth's impact.

- **TELEHEALTH:**

- **Medicare**

- Most of the current Medicare telehealth flexibilities that Medicare beneficiaries have relied on over the past two years will remain in place through December 2024 due to the Consolidated Appropriations Act, 2023 passed by Congress in December 2022, such as:
 - Access to telehealth services in any geographic area in the United States, rather than only those in rural areas.
 - Receive in-home telehealth visits that Medicare pays for rather than traveling to a health care facility.
 - Cover certain telehealth visits delivered audio-only (such as a telephone) if someone is unable to use both audio and video, such as a smartphone or computer.
 - Medicare Advantage plans may offer additional telehealth benefits.

- Additionally, after December 31, 2024 when these flexibilities expire, some Accountable Care Organizations may offer telehealth services that allow primary care doctors to care for patients without an in-person visit, no matter where they live.
- **Medicaid**
 - States have significant flexibility with respect to covering and paying for Medicaid services delivered via telehealth. State requirements for approved state plan amendments vary as outlined in CMS' Medicaid & CHIP Telehealth Toolkit. This flexibility was available prior to the COVID-19 PHE and will continue to be available after the PHE ends. Like Medicare, these telehealth flexibilities provide a vital lifeline to many individuals receiving Medicaid, particularly for persons in rural areas and those with limited mobility.
- **Private Insurance**
 - During the PHE, high deductible health plans were granted a temporary safe harbor to cover telehealth and remote care services on a first dollar basis without jeopardizing Health Savings Account contributions. This safe harbor has been extended through December 31, 2024 due to the Consolidated Appropriations Act, 2023.

Questions:

Q: How will the transition from the public health emergency affect Medicaid Telehealth? budget?

- Under Medicaid statute, telehealth is a mode of delivery, not a separate services. States have flexibility to continue pandemic changes they may have made under current law.

Q: Why does the HHS budget not permanently extend telehealth flexibilities in Medicare?

- HHS is committed to supporting a temporary extension of some broader telehealth coverage flexibilities under Medicare beyond the COVID-19 Public Health Emergency. However, we also support Congressional mandates to study whether Medicare's telehealth flexibilities promote proper use and access to care. Additionally, HHS continues to work closely with Congress to provide technical assistance on several introduced telehealth bills and others that are in development. We urge Congress to extend permanently several high priority Medicare telehealth provisions:
 - (1) Coverage of services with the patient's home as an originating site;
 - (2) Federally Qualified Health Centers and Rural Health Clinics provisions allowing both to serve as distant sites;
 - (3) Payment parity for behavioral telehealth services, based on strong evidence that telehealth is as effective as standard in-person treatment in this area; and
 - (4) Audio-only access for patients whose circumstances necessitate that as the preferred mode of care delivery (whether due to broadband limitations, lack of video-enabled devices, data limitations, and/or beneficiary preference).

Q: What telehealth flexibilities remain in Medicaid after the PHE ends?

- States generally have broad flexibility to cover and pay for services provided via telehealth in their Medicaid program. States may apply to CMS for waivers or state plan amendments to continue telehealth flexibilities that expire as a result of the end of the PHE.

Q: What telehealth flexibilities remain in Marketplace plans after the PHE ends?

As is currently the case during the PHE, coverage for telehealth and other remote care services will vary by private insurance plan after the end of the PHE. When covered, private insurance may impose cost-sharing, prior authorization, or other forms of medical management on telehealth and other remote care services.

Public Health Emergency - Unwinding

TALKING POINTS:

- While COVID is not over, because of the Biden Administration's whole of government response since day 1, we distributed over **965 million vaccines**, and now we are in a position where we can effectively lift the Public Health Emergency (PHE) and the National Emergency.
- The Administration will now execute the process of a smooth **operational wind down** of those emergency policies enabled by the COVID-19 emergency declarations, including waivers that give healthcare providers and systems the flexibilities needed for operations and staffing to provide expanded and continued access to high quality of care.
- Over the past year, HHS divisions have taken over **100 actions** to support outreach on unwinding, including webinars, Dear Colleague Letters (DCLs), technical assistance, social media efforts, e-newsletters, and blog spots.
- We will continue to communicate to States, health care providers, and the public in the coming days and months, what that process means and working with states and jurisdictions to ensure an orderly transition.

QUESTIONS:

Q: How will this impact the uninsured?

- This decision to unwind the PHE and lift the National Emergency is distinct from our longer-term planning on the transition of vaccines and additional therapeutics to the commercial market.
- Right now, COVID-19 vaccines and certain therapeutics remain free and widely available. We will be transitioning to commercial markets later this year, but making sure that the uninsured have continued access to vaccines and treatments is one of the Administration's highest priorities.

Q: What about 1135 waivers? What about telehealth?

- CMS has been working with stakeholders over the last few months to understand the flexibilities enabled by these 1135 waivers and other mechanisms and plan for their eventual end.
- Last August, CMS developed a roadmap for the eventual end of the waivers and flexibilities, and shared information on what health care facilities and providers can do to prepare for future events.
- Similar to the guidance CMS has made available to states, CMS released fact sheets that will help the health care sector transition to standard operations once the PHE ends.

- Regarding telehealth, certain major flexibilities in Medicare coverage for certain telehealth services will remain in effect through at least December 31, 2024.
- However, ending the PHE would terminate flexibilities in the prescribing of certain controlled substances via telehealth. The Drug Enforcement Administration Has proposed rulemaking in this area, and we look forward to working with our DOJ colleagues and stakeholders on a final rule.

Q: What data powers does this relinquish?

- The PHE has facilitated our monitoring of variants by allowing the Centers for Disease Control and Prevention (CDC) to impose requirements for data reporting.
- CDC has been working with jurisdictions to continue to voluntarily provide data; the wind down will give CDC the time that it needs to continue to negotiate agreements with all jurisdictions.

Q: What is the timeline for commercialization of the COVID-19 vaccines and treatments?

- While there are many considerations and timelines may shift based on the trajectory of the virus, we anticipate that the transition of vaccines to more traditional pathways for procurement, distribution, and payment will occur in early fall.
- Some of those considerations include what will be authorized and recommended by FDA and CDC, and what will align with a strain change for potential variants.
- Provided that one is authorized and recommended by FDA and CDC, we expect this transition will align with a possible strain change that accounts for any potential variants.
- The treatments transition to commercial markets will vary by product and will likely occur for at least one product before the end of the year.
- The USG is working on determining the exact dates for COVID-19 vaccines and therapeutics. We will share more information about timelines when we are able.

Q. What is the impact of the end of the COVID-19 Public Health Emergency (PHE) on May 11 on access and costs to COVID-19 vaccines and treatments?

- The PHE does not affect the transition of vaccines and treatments to commercial markets.
- In February 2023, HHS Secretary Becerra renewed the PHE for one last 90-day period planned to end at the end of the day on May 11, 2023. This action is based on the most recent COVID-19 trends and is consistent with the Administration statement on January 30, 2023, that the PHE is planned to end at the end of the day on May 11.

- In the past, HHS has committed to providing 60 days-notice in advance of ending the PHE. To foster a smooth transition, HHS has given 90 days-notice instead.
- Even with the planned end of the PHE at the end of the day on May 11, on May 12, all vaccines and treatments purchased by the U.S. government will continue to be distributed and available for free to U.S. residents. The PHE itself does not affect the supply or distribution of our vaccines or treatments. It also does not affect FDA's ability to authorize various products, including tests, treatments, or vaccines for emergency use.

Q. How will commercialization change the accessibility of COVID-19 vaccines and treatments?

- COVID-19 remains a significant public health priority for the Administration and for HHS. We know so many are still affected by COVID-19, particularly seniors and people with disabilities. We remain committed to maximizing availability of COVID-19 vaccines and treatments.
- Our intention is that vaccines and treatments will remain available from all of the places U.S. residents currently receive them, whether it's at their pharmacy or their health care provider.
- Vaccines will remain free for most U.S. residents through the Vaccines for Children Program, Children's Health Insurance Program, most commercial insurance, Medicare, and Medicaid programs.
- Those with Medicare, Medicaid, and most private insurance will be able to access covered treatments, potentially with cost-sharing.

Q. How will Vaccines be available for the un- and under-insured?

- CDC's Vaccines for Children Program will provide coverage for uninsured children as it does for other routine vaccinations.
- HHS is actively working with vaccine and treatment manufacturers to ensure that Patient Assistance Programs that provide free access to these products are easy to use and broadly accessible.
- HHS continues to invest in health systems and programs that support vaccine access and outreach in underserved communities such as Federally Qualified Health Centers, Rural Health Clinics, and state and local health departments. These networks can be leveraged for access to COVID-19 vaccines and therapeutics as well as other needed medicines.

Physician Payments

TALKING POINTS:

- HHS values the critical role that physicians and other health care professionals play in health care delivery.
- Ensuring adequate Medicare payments for providers is essential to maintain beneficiary access to high-quality and affordable health care.
- I appreciate Congress' leadership in the Consolidated Appropriations Act, 2023 to (1) provide temporary, one-year increases payment amounts for all services under the physician fee schedule by 2.5 percent in 2023 and 1.25 percent in 2024 and (2) extend incentive payments for clinicians who are qualifying participants in advanced alternative payment models for one year through 2025, though at a lower rate (3.5 percent rather than 5 percent).

QUESTIONS:

Q: Medicare cuts in physician payments are driving health system consolidation, exacerbating provider shortages and access issues, and hurting our health system's responsiveness and capabilities for future pandemics. Why did CMS cut physician payments again for 2023?

- The Biden-Harris Administration is committed to protecting and strengthening Medicare so that Americans of every generation can count on it and ensuring that providers receive appropriate payments is a critical part of our efforts.
- HHS is required to base payments for services under the physician fee schedule on the relative resource costs involved in furnishing a service, and the fee schedule is subject to statutory budget-neutrality requirements.
- HHS does not have the legal authority to implement increases in payment outside of budget neutrality without additional action taken by Congress.

PrEP Delivery Program to end HIV Epidemic

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
PrEP Delivery Program Cost	-	237	+237
Total Program Level	-	237	+237

Note: The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year.

TALKING POINTS:

- The budget includes a mandatory proposal to invest \$9.8 billion over 10 years to create a national financing and delivery program so anyone who needs Pre-exposure Prophylaxis (PrEP) has access via community providers.
- Fewer than 1 in 4 people who could benefit from PrEP are receiving the medication. Preliminary CDC data show that only 9 percent of the nearly 469,000 Black individuals who could benefit from PrEP received a prescription in 2020 and only 16 percent of the nearly 313,000 Hispanic and Latino individuals who could benefit from PrEP received a prescription.

QUESTIONS:

Q: The Budget includes a new PrEP for All proposal. What will happen to the current PrEP donation program?

- The PrEP for All proposal builds on the current donation program to expand its benefits and purposes to meet anyone in need of care.

Q: What is the future cost of this program?

- The program invests \$9.8 billion over the next ten years to expand access to PrEP for individuals at high risk of HIV infections across the United States.

Q: Will this program end the HIV/AIDS epidemic?

- The program aims to end the HIV/AIDS epidemic by 2030, with a commitment to 75% infection reduction by 2025.

Program Integrity

(Dollars in Millions)

Activity	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Discretionary HCFAC			
CMS	666	667	+1
ACL ¹	0	35	+35
OIG	105	112	+7
DOJ	122	122	+0
Subtotal, Discretionary HCFAC	893	937	+44
Mandatory HCFAC	1,523	1,812	+289
Total, HCFAC Program Level	2,416	2,749	+333
Medicaid Integrity Program	95	100	+5

¹ACL's FY 2023 Enacted amount (\$35 million) for the Senior Medicare Patrol program is included in CMS's FY 2023 Enacted amount.

TOPLINE MESSAGES:

- The budget includes \$5.2 billion² in new investment over ten years in combined mandatory and discretionary Health Care Fraud and Abuse Control (HCFAC) spending.
- This robust investment in fraud prevention and enforcement will yield a return-on-investment of \$19.7 billion over ten years.
- Increased investment is needed to keep pace with the size, scope and complexity of healthcare fraud.
- Without additional resources, CMS, the HHS Office of Inspector General, and DOJ may have to forgo investigating serious instances of fraud, waste, and abuse.

QUESTIONS:

Q: Why are you seeking such a large increase in HCFAC funding? Is this an indication that the Administration has allowed healthcare fraud to run rampant?

- No. The increase in HCFAC funding reflects the Administration's commitment to fighting fraud and the belief that this investment will pay off in significant returns to Medicare Trust Funds and the Treasury.

² The printed draft of the Budget in Brief has an error showing this number as \$5.5 billion rather than the correct figure of \$5.2 billion; the on-line version of the BIB will correct that error.

- Growth in Medicare and Medicaid benefit spending has been more than double growth in HCFAC oversight spending in the last four years alone.
- Additionally, this funding is necessary to keep pace with the growing scope and complexity of fraud schemes.
- This investment will more than pay for itself. Medicare program integrity activities currently yield an \$8 to \$1 return-on-investment. Law enforcement program integrity activities currently generate a \$4 to \$1 return-on-investment.
- Our budget makes the biggest investment in health care fraud and abuse prevention and enforcement since the Affordable Care Act. We increase spending to combat health care fraud and abuse by 20 percent over ten years, compared to the 5 percent increase Congress provided for this activity in 2010. That is a four-fold difference. About two-thirds of the funding increase goes toward prevention, one-third toward enforcement.

Provider Relief Fund

TALKING POINTS:

- The Provider Relief Fund (PRF) was developed and launched mere weeks after the CARES Act passed, at the height of the initial challenges related to the pandemic and at a time of great uncertainty surrounding the impact that COVID-19 would have on the health care system.
- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding. This includes:
 - \$15.4 billion to over 90,000 providers in Phase 4
 - \$8.3 billion in ARP Rural payments to 47,000 providers with patients who live in rural areas
 - Nearly \$20 billion to about 65,500 providers through Phase 3
 - About \$13 billion to safety net hospitals
 - Almost \$21 billion to providers in “COVID-19 Hotspots” at different times during the pandemic
 - Nearly \$5 billion to skilled nursing facilities
- The Biden-Harris Administration implemented Phase 4 of the PRF allocations after the prior Administration had allocated most of the funds. In this Administration, we have focused on distributing PRF payments in a way that recognizes providers’ public payor mix and as efficiently as possible while ensuring transparency and program integrity to safeguard taxpayer dollars.
- To date, of the 106,000 applications received, HHS has **processed more than 99% of Phase 4 applications** and **100% of applications for rural** providers in the American Rescue Plan funding.

QUESTIONS:

Q: How much money is left in the Provider Relief Fund?

- All funding is fully allocated. Balances are supporting ongoing activities.
- HHS has allocated resources to reimburse health care providers for the cost of COVID-related health care through the Provider Relief Fund program. HRSA conducts a thorough, multi-step process to evaluate and verify provider claims and requests for reconsiderations. While most funds have been obligated, in some instances, HRSA’s process is not yet complete. Congress made these funds available until expended. HRSA obligates funds as payments are made.

Q: Why did HHS use PRF funds to promote vaccine confidence and vaccine outreach campaigns in December 2022?

- The campaigns launched in December 2022 supported the uninsured and most vulnerable population in accessing COVID vaccines. HHS utilized available funds to support access to critical COVID services during the winter months.

Q: Why is HHS sending debt collection letters to providers for Provider Relief Fund payments?

- PRF recipients are required to comply with reporting requirements established under the CARES Act.
- Providers who do not meet their reporting requirements or who are otherwise found out of compliance with the Terms and Conditions are subject to repayment of the funds.
- HHS has begun issuing Final Repayment Notices to providers who are non-compliant with the PRF Terms and Conditions.
- Providers who disagree with the repayment request have an opportunity to request a Decision Review of HHS's decision to seek recovery of PRF funds. Information on how providers may request a Decision Review will be included in the Final Repayment Notice.

Q: Why did PRF payments appear to benefit providers that were in stronger financial positions at the start of the pandemic?

- Due to the unprecedented nature and uncertainty at the beginning of the pandemic, Congress directed that HHS distribute PRF funds using "the most efficient payment systems practicable to provide emergency payment."
- As a result, HHS used provider data that was readily available, including data already used by HHS agencies, or could be quickly and consistently collected to ensure that payments would be issued swiftly so the health care system could be kept afloat at a time when many health care providers were experiencing an unprecedented and abrupt loss in revenue.
- Ensuring equity and transparency in PRF payments has been a top priority for me.
- Under my leadership, we developed and implemented Phase 4 of the Provider Relief Fund. Phase 4 prioritized equity for providers serving high need communities, including by incorporating bonus payments based on the number of services provided to patients with Medicaid, Children's Health Insurance Program (CHIP), or Medicare coverage, who tend to have greater and more complex medical needs or have lower incomes.

Quality Adjusted Life Years (QALYs)

TALKING POINTS:

- Across HHS, we are working every day to address the health disparities of disabled people and ensure equal access to health care for everyone.
- There is already a prohibition on the use of quality adjusted life years in Medicare, and HHS is in full compliance.
- We are happy to work with Congress and provide technical assistance on legislation related to the use of quality adjusted life years.

If pressed on drug price negotiation

- The Inflation Reduction Act prohibits the Secretary from using quality adjusted life years for drug price negotiation.
- We will follow the statute.

Refugees and Unaccompanied Children – Budget Overview

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Transitional and Medical Services	564	1,000	+436
Refugee Support Services	307	686	+379
Unaccompanied Children	5,506	5,506	--
FY 23 Supplemental Funds	2,400	--	-2,400
FY 23 CR Anomaly Funds	1,775	--	-1,755
Contingency Funds ¹	<u>326</u>	<u>2,776</u>	<u>+2,450</u>
Subtotal, UC & Refugees	10,878	9,969	-910
Trafficking Victims and Torture Survivors	50	66	+17
Total Program Level²	10,928	10,035	-893

¹ Funding amounts are based on probabilistic scores

² FY 2023 includes \$2.4 billion in Division M (Ukrainian Supplemental) funds which are not included in budget authority.

TALKING POINTS:

- The budget provides \$10.0 billion for new arrivals and unaccompanied children. An expanded contingency fund would provide additional resources if needed for either population.
- Refugees: Continues to **rebuild the nation's resettlement capacity** by requesting an increase of +\$815 million to support 241,000 eligible new arrivals in FY 2024, including 125,000 refugees.
 - Including the contingency fund, the Budget would support 426,000 new arrivals.
- Unaccompanied Children: **Protects** unaccompanied children, moving them from the DHS border facilities to child center care settings, keeping them safe from COVID, and uniting them safely and quickly with vetted relatives or other sponsors.

QUESTIONS:

Q: Does your budget include sufficient funds to shelter all new arrivals and unaccompanied migrant children?

- Budgeting for this program is challenging because we do not know how many people will need services in FY 2024. Because these estimates may change, it also includes a

contingency fund to ensure we can respond to the unpredictable and sometimes rapidly changing nature of these populations.

- Protecting unaccompanied migrant children can be costly given their complex needs and various legal and ethical requirements. We are focused on being good stewards of tax dollars without cutting corners when it comes to the well-being of children in our care. We also owe new refugees, asylees, and other arrivals a chance to become self-supporting in their new home country.
- The budget includes sufficient discretionary funds to provide initial support for 241,000 new refugee, asylee, and other arrivals and for 16,000 standard shelter beds.
- If additional resources are needed for either population, the Budget proposes an expanded version of the contingency fund Congress enacted in FY 2023.
 - Unaccompanied Children: Funds would be provided if monthly arrivals exceed 10,000 in FY 2024.
 - New Arrivals: Funds would be provided if the number of Asylees and Cuban and Haitian entrants exceeds 150,000 in FY 2023 or 75,000 in FY 2024. Unlike refugees, these populations are not subject to a ceiling.

Q: Will HHS need a supplemental or be deficient before the end of FY 2023?

- I appreciate the question. I would like to express my gratitude to Congress for providing \$10.9 billion for refugees and unaccompanied children in the FY 2023 Omnibus, \$2 billion more than the FY 2022 amount and for approving a contingency fund for Unaccompanied Children. That said, arrival numbers through February have been as high as they were in FY 2022 and the future impact of title 42 termination on referral numbers is uncertain. We will continue to assess our funding needs and operational options, and to communicate with the Congress.

Q: What is HHS doing to combat child labor exploitation among unaccompanied children?

- HHS continues to work hard to protect the safety and wellbeing of unaccompanied children by providing them child-centered care while they are in our custody and follow up services after they are released. Last month, the Departments of Labor and Health and Human Services announced a series of actions to increase their efforts to thoroughly vet sponsors of migrant children, investigate child labor violations, and hold the companies accountable. HHS activities include:
- **Mandated Follow Up Calls for Unaccompanied Children Who Report Safety Concerns:** HHS will require a follow-up call to any child who calls the Office of Refugee Resettlement National Call Center with a safety concern.
 - The Center currently refers every safety related call to the appropriate law enforcement or child protective services agency.
 - This additional call will serve as a critical follow up with the child.

- **Expand Post Release Services for Unaccompanied Children:** HHS continues to increase the percentage of children receiving services and to improve their quality.
 - HHS provided post release services to more than 40 percent of discharged children in FY 2022, nearly double the percentage receiving services when the Biden Administration took office. HHS is on track to provide services to all children who would benefit from post release services within the next two years.
 - Additional post release services include assistance in registering children for school, ensuring they understand the immigration legal process and can attend their court hearings, and help finding medical, mental health, and family counseling services for which they may be eligible.
 - ACF will publish a new grant announcement this spring, expanding *eligibility* for post release services to all discharged children and establishing a new service level for specific challenges or special circumstances (e.g., medically or psychologically vulnerable children, family conflict or crisis, education-related issues).
 - **Audit Sponsor Vetting Process:** HHS is auditing the vetting process for potential sponsors who have previously sponsored an unaccompanied child to ensure all necessary safeguards are in place without unnecessarily keeping children in shelter care.
 - This audit builds on steps that HHS has already taken to increase vetting of those types of sponsors and includes updates to data systems to identify such cases more easily.

Refugees - Afghan/Ukrainian

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Transitional and Medical Services (TAMS)	564	1,000	+436
Refugee Support Services	307	686	+379
CR Emergency Supplemental	1,775	0	-1,775
Division M Supplemental	2,400	0	-2,400
Contingency Fund	326	2,776	+2,450
Trafficking Victims and	31	39	+9
Torture Survivors	19	27	+8
Total Program Level, Refugees¹	5,442	4,529	-893

¹ Excludes funds for Unaccompanied Children

TALKING POINTS:

- In the 18 months since the launch of Operation Allies' Welcome (OAW), the U.S. has welcomed approximately 94,000 individuals from Afghanistan, and over 120,000 Ukrainians are part of Uniting for Ukraine (U4U) all eligible for ORR benefits and services.
- ORR continues to fund services through the \$2.9 million ASA supplementals and a \$900 million supplemental supporting Ukrainian arrivals. These supplementals have provided cash and medical assistance, emergency housing, support for schools and enhanced mental health services.
- We are working to support longer-term housing and support legal assistance to Afghans as they pursue permanent asylee status.

Refugees - Cuban/Haitian/Venezuelan Parole Program

TALKING POINTS:

- ORR strives to ensure equitable access to benefits and services for all ORR-eligible individuals. Cuban and Haitians coming through the new parole program are eligible for ORR services supporting their path to self-sufficiency.
 - Over 20,000 Cuban and Haitians have arrived through the new parole program.
 - The FY24 budget assumes 241,000 new arrivals eligible for refugee benefits for the year, including 116,000 non-refugee arrivals such as Cuban and Haitian entrants.
 - These individuals are eligible for ORR refugee benefits and services and are also eligible to apply for work authorization and a Social Security number.

If pushed on FY203 supplemental funding:

- ORR received \$2.4 billion in FY 2023 supplemental funding to support the impact of increased arrivals as well as unaccompanied children. ORR is working to allocate these funds to impacted areas providing cash and medical assistance and other Refugee Support Services to include employment and language supports.
 - Budgeting for these programs is challenging because the number of people they serve fluctuates. The budget request includes a contingency fund which could provide support to 426,000 new arrivals.

Reproductive Health

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Title X Family Planning (HRSA Discretionary)	286	512	+226
Teen Pregnancy Prevention (GDM Discretionary)	101	111	+10
Sexual Risk Avoidance (GDM Discretionary)	35	--	-35
Embryo Adoption Awareness Campaign (GDM Discretionary)	1	1	--
Teen Pregnancy Prevention Program Evaluation (PHS Evaluation Funds)	7	8	+1
Total Program Level	430	632	+202

TALKING POINTS:

- Since Title X was created, **more than 195 million predominantly low-income clients** have received quality healthcare through Title X as their usual source of medical care, including the services, information, and referrals, that higher-income clients and clients with private insurance get.
- 3,284 community-based sites have provided clinical and educational services to **over 1.7 million persons** in 2021 (most recent year available) through 2.8 million family planning encounters.
- Title X has long been the gold standard of family planning care, and this administration has re-doubled its **emphasis on quality by realigning the program's requirements with national clinical recommendations** on delivering quality family planning services.
- Title X offered cervical and breast cancer screening services to over 320,000 female users and funds sexually transmitted disease and HIV testing for preventing disease transmission and adverse health consequences.
- In 2021, 86% of clients had family incomes at or below 250% of the FPL, and 65% of all clients were entitled to free services with incomes at or below 100% FPL.

QUESTIONS:

Q: Why is the Sexual Risk Avoidance program being eliminated in FY24?

- Proponents of adolescent health, including prevention of teenage pregnancy, strongly oppose this program because of the lack of evidence that it works and have expressed concern that it could rather have adverse impact on overall teenage health and behavior. The FY24 budget shifts this funding into the evidence-based Teen Pregnancy Prevention program and Title X Family Planning program, continuing support for vulnerable populations with proven and effective programming.

Q: Will these funds be used to provide abortion services?

- The Title X program does not provide abortion services. Section 1008 of the Public Health Service Act specifically states that “None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.” Consistent with the program’s statute and regulations, any public or private nonprofit organizations, including faith-based organizations, state, county, local, and tribal governments, school districts, and public and state higher education institutions are eligible to apply for Title X grant funds. Title X’s regulations also clearly define the criteria the Department uses to decide which family planning services projects to fund and in what amount.

Q: The 2021 Title X final rule argued that it was necessary to restore and expand access to Title X family planning services. Has the administration succeeded in getting new providers and what is the impact on funding for loyal family planning grantees that did not leave the program since there was no increase in funding?

- The demand for Title X funding for highly qualified providers to deliver care in communities far exceeds the resources available.
 - A federal study from 2016 estimated that Title X would need \$737 million to serve just all of the women in need of Title X care.
 - The reality is that it has been eight years since there was an increase for Title X through the annual appropriations process.
 - As a result, the Department has had to make tough choices with a focus on ensuring that as many clients in as many communities can get the quality family planning care they want and need.

Q: What is HHS doing to protect individual’s rights to reproductive care as we see attacks across the country?

- HHS has taken several meaningful actions under the Biden-Harris Administration to protect and bolster reproductive health, rights, and justice.
 - In October 2021, we issued a final rule for the nation’s family planning program to strengthen access to equitable, affordable, client-centered, and high-quality family planning services nationwide.
 - In January 2022, we announced \$6.6 million for the Title X planning program to address demand for family planning services where restrictive laws and policies have impacted reproductive health access.

Q: Maternal Mortality surged by nearly 20% during the first year of COVID-19 (2020), and the gap between black and white maternal mortality grew. What is HHS doing to reduce these disparities and address this maternal crisis in the US?

- This is a key priority for me personally and the Biden-Harris Administration.
 - Thanks to the American Rescue Plan, we have worked with states to expand Medicaid coverage of postpartum health care for 12 months. Illinois, Georgia, Missouri, New Jersey and Virginia have led this important initiative.
 - We increased funding for Enhancing Reviews and Surveillance to Eliminate Maternal Mortality Program to reach six additional states, for a total of 30 awards supporting 31 states. This funding directly supports agencies and organizations that coordinate and manage Maternal Mortality Review Committees (MMRCs) to identify, review, and characterize pregnancy-related deaths; and identify prevention opportunities.

The 2021 Title X final rule revoked requirements of the 2019 regulations, including removing restrictions on nondirective options counseling and referrals for abortion services and eliminating requirements for strict physical and financial separation between abortion-related activities and Title X project activities. Will this change lead to use of federal funds to pay for or promote abortion services?

- The 2019 Trump Administration regulations substantially diminished the Title X family planning network by forcing requirements inconsistent with nationally recognized clinical recommendations. The impact of both the Trump Administration's regulations and the pandemic led to a drop in the number of clients served from 3.9 million to 1.5 million people. The new regulations restore many aspects of the program that were removed through the Trump administration regulations.
- The final Biden Administration Title X regulations allows all highly qualified family planning providers, including clinics like Planned Parenthood that provide abortion services outside of Title X with non-federal funds, to once again apply for federal support to provide family planning services to low-income and uninsured individuals.
- Advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, is a priority for the Administration, including the Title X program and the Department. This 2021 regulation will allow for the Title X service network to expand in size and capacity to provide quality family planning services to more clients.
- As outlined by the Title X statute and reinforced in its regulations, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." Consistent with the program's statute and regulations, any public or private nonprofit organizations, including faith-based organizations, state, county, local, and tribal governments, school districts, and public and state higher education institutions are eligible to apply for Title X grant funds. Title X's regulations also clearly define the criteria the Department uses to decide which family planning services projects to fund and in what amount.

Return to Work

TALKING POINTS:

- The COVID-19 pandemic reshaped the workplace for many Americans, including federal employees at HHS.
- While COVID-19 is no longer a determining factor for how we do our work, the pandemic has forever changed both the public and private sectors' approaches to the way work is done. Hybrid work environments have allowed federal agencies, including HHS, to stay competitive with other sectors, ensuring we are recruiting and retaining the best talent to help meet the needs of the American people.
- Federal agencies, including HHS, are strategically using personnel policies like telework, remote work, and flexible work schedules to advance their missions and better compete in the national labor market to attract and retain a well-qualified and engaged federal workforce.

QUESTIONS:

Q: How many days were you personally in the office last week?

- I can assure you that this is a 24/7 job and I treat it as such, whether I am in the office or the on the road helping advocate and elevate the work of HHS and our incredible divisions.

Q: In last year's SOTU, President Biden said "the vast majority of federal workers will once again work in person." Yes or no, are the vast majority of your employees working fulltime in person today?

- Our employees are working fulltime.
- HHS is unique in that the Department has thousands of mission critical employees who never left their worksites, even at the height of the COVID-19 pandemic. Together with those employees working remotely, HHS continues to meet its mission for the American public.
- Some individuals are on-site full-time, the majority of the workforce reports to their workplace every pay period, and some workers are fully remote. Regardless of an employee's physical location, they continue to work hard every day to carry out the mission of HHS.
- I would also note that we have scientists in labs and service providers in the field working hard every day who may or may not be regularly logging into systems, depending on their work's needs.
- *If pressed on numbers:* I do not have those numbers on hand and would note this is not a static situation.

Q: Do you believe HHS's mission is hindered by having so many employees working remotely?

- In just the last two years, HHS and its operating divisions have accomplished incredible work for the American people, including:
 - The roll-out and distribution of 294 million vaccines doses to 75,000 sites across the country as well as 670 million at-home COVID-19 test kits-.
 - The largest and most successful open enrollment to date in 2022 with 14.5 million people signed up for or enrolled in Marketplace coverage.
 - Increased provider access to buprenorphine, the medication assisted treatment for opioid use disorder, by 21% from 2021 to 2022.
 - Transition to the 988-suicide prevention lifeline – an easy-to-remember number for 24/7 crisis care.
- All these accomplishments, which are just a snapshot of HHS' work, occurred while the agency offered a telework or hybrid posture for some employees. These milestones reflect how the Department continues to deliver for the American people and promote the health and well-being of the nation.

Rural Health

	FY 2023	FY 2024	
	Enacted	President's Budget	+/- FY 2023 Enacted
Rural Health Policy Development	11,076	11,076	-
Rural Health Outreach Grants	92,975	95,375	+2,400
Rural Hospital Flexibility Grants	64,277	64,277	-
State Offices of Rural Health	12,500	12,500	-
Radiation Exposure Screening and Education Program	1,889	2,734	+845
Black Lung	12,190	12,190	-
Rural Communities Opioid Response	145,000	165,000	+20,000
Rural Residency Planning and Development	12,500	12,700	+200
Rural Health Clinic Behavioral Health Initiative	-	10,000	+10,000
Financial and Community Sustainability for At-Risk Rural Hospitals	-	10,000	+10,000
The Rural Hospital Stabilization Pilot Program	-	20,000	+20,000
Subtotal, Federal Office of Rural Health Policy	352,407	415,852	+63,445

TALKING POINTS:

- Health care should be accessible, no matter where you live.
- The Biden-Harris Administration is dedicated to improving access to health care in rural communities and addressing the issues which contribute to health inequities impacting these communities.
- Thanks to Congress's leadership in the Consolidated Appropriations Act of 2021, CMS has implemented a new Medicare provider type, the Rural Emergency Hospital. Applications are available now for hospitals in rural areas that would like to change to this new provider type.
- Over the last two years, through the Rural Communities Opioid Response (RCORP) program, we have served over two million rural individuals.

- The President's Budget seeks to support and expand these programs to ensure every person has the same level of care no matter their zip code.

QUESTIONS:

Q: We have seen large increases in costs for hospitals, including labor costs. Are you aware of this issue, and do you believe it may be time to update the method for reimbursing hospital labor costs to better reflect new staffing practices?

- HHS is committed to promoting Medicare payment accuracy and hospital stability.
- In computing the Hospital Wage Index, CMS follows a process established by law. In applying the law, CMS strives to ensure access for all beneficiaries while maintaining incentives for the agency's hospital partners to operate efficiently.
- The goal of the hospital wage index is to adjust hospital payment rates to account for local differences in the wages.

Q: Which telehealth services will no longer be covered under Medicare after the public health emergency is over?

- Thanks to the Consolidated Appropriations Act of 2023, many telehealth flexibilities available during the public health emergency have been extended through December 31, 2024.
- *If needed:* I would be happy to have my colleagues in CMS follow up with you on questions about specific waivers.
- For over 36 years, HHS has played a leading role in improving the health and well-being of rural Americans.
- HHS funds a range of programs that directly support rural communities to increase access to care in rural communities, build the infrastructure necessary to implement the services, and train and expand the workforce in rural communities.
- Additionally, HHS supports the only federal research program specifically focused on rural health issues.
- Our Budget requests a \$63 million increase for rural programs, which is critical amid ongoing challenges of health care access and disparities.

Q: How does HHS plan to utilize the requested budget increase for rural health programs?

- HHS is requesting \$20 million to continue to support substance use disorder prevention and treatment in rural communities including the creation of new medication assisted treatment access points and equipping first responders with naloxone.
 - o The Rural Communities Opioids Response program funds prevention, treatment, and recovery services in rural communities, serving over two million rural individuals between 2021 and 2022.
 - o We plan to reach even more rural individuals with this increased funding.

- In addition, we are requesting \$40 million for three new programs to meet the unique health needs of rural communities as they face hospital closures and service reductions exacerbating disparities in access to care.
 - o \$10 million for the Rural Health Clinic Behavioral Health Initiative which aims to expand access to behavioral health care services at Rural Health Clinics;
 - o \$10 million for Financial and Community Sustainability for At-Risk Rural Hospitals which targets technical assistance to rural hospitals at-risk for closure; and
 - o \$20 million for the Rural Hospital Stabilization Pilot Program to enable at-risk hospitals to expand their services, such as obstetric services, chemotherapy, and more, to create new care in the community while expanding revenue streams to stabilize operations and meet local needs.

Shortages/Supply Chain Issues

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	10	22	+12

¹ Funding is specific to continue building capabilities for the supply chain and shortages program for medical devices.

TALKING POINTS:

- We continue to take steps to closely monitor the supply chain and address shortages to help protect Americans' access to critical medical products. As you know FDA is limited in its authorities to prevent and resolve shortages.
- Right now the FDA can:
 - Assist with production by expediting reviews of new marketing submissions, production lines, or material sources to increase production;
 - Extend Product expiration dates by reviewing requests for extensions of product expiration dating; and
 - And exercising temporary regulatory flexibility and discretion.
- The budget invests **\$26 million** in ongoing efforts to modernize the agency's safety surveillance and oversight program, mitigate supply chain interruptions, and enhance active surveillance system for medical devices.
- We are also requesting important new authorities to enhance FDA's ability to forecast, prevent and resolve the supply chain challenges. Such as a requirement for manufacturers to alert FDA when there is an increase in demand of a product, as we saw this past year.

QUESTIONS:

Q: How does the Agency prevent or respond to drug shortages?

- As a result of presidential, congressional, and FDA actions, drug manufacturers are notifying FDA earlier than in the past about certain manufacturing interruptions and discontinuances.
- These early notifications give FDA additional time to work with manufacturers and other stakeholders to identify ways to maintain treatment options and prevent or mitigate a shortage.
- FDA helps prevent and resolve drug shortages in various ways such as: expediting reviews of new production lines or material sources to increase production; reviewing requests for extensions of product expiration dating; and exercising temporary regulatory flexibility and discretion.

- FDA has been able to help prevent shortages, but we are seeing continued challenges and hearing from manufacturers frequently about potential disruptions in their supply and from patients who cannot find the medical products they need.
 - Manufacturers are not expressly required to notify FDA when a shortage is due to increased demand.
 - Having early indication of increases in demand may allow the Agency to better utilize our authorities associated with drug shortages and work with manufacturers to help avoid unnecessary drug shortages driven by demand.
 - Many underlying causes of shortages are likely related to economic/market forces that go beyond a regulatory agency's jurisdiction. FDA cannot order manufacturers to continue making a product or to make more of the product. Nor can FDA tell them how to distribute their products.

Q: How does the Agency prevent or respond to device shortages?

- FDA's authorities for medical device shortages remain limited.
- As a result of the CARES Act of 2020, manufacturers of critical devices have, during the COVID-19 public health emergency, been notifying FDA about certain manufacturing interruptions and discontinuances.
 - These notifications have given FDA more timely information to work proactively with manufacturers and other stakeholders to identify alternative sources of raw materials and device components and work through other supply chain issues.
- FDA helps prevent and mitigate device shortages in various ways such as: expediting reviews of new marketing submissions, expediting inspections, granting emergency use authorizations, and exercising temporary regulatory flexibility
- During the public health emergency, FDA used the information we collected under these new authorities to help prevent or mitigate approximately 350 of the 455 device shortages or potential shortages that emerged.
 - Unfortunately, FDA's authority to require notifications from manufacturers of critical medical devices is temporally limited to "during or in advance of" a public health emergency, and will lapse when the public health emergency declaration expires.
 - COVID-19 also showed us that manufacturers are not always prepared for situations where their ability to manufacture product may be disrupted or may be insufficient to meet increases in demand. Providing FDA clear authority to review risk management plans (RMPs) would help ensure resiliency and mitigate future supply chain disruptions.

State Opioid Response (SOR) Grants

TALKING POINTS:

- Since the State Opioid Response (SOR) program began, approximately 1,148,900 patients have received treatment services, including almost 553,350 who have received an FDA-approved medication for opioid use disorder.
- The budget provides \$5.7 billion for SAMHSA's substance use prevention and treatment activities, an increase of \$1.3 billion over FY 2023 enacted, funding states and territories to increase access to treatment for substance use disorder, advance public-health interventions like naloxone, and expand recovery support services.
- The budget request for the SOR program at the FY 2024 budget level (\$2 billion) would enhance states' ability to address opioids and stimulants and respond to the overdose epidemic that have been exacerbated due to the COVID-19 pandemic.
- We understand the importance of avoiding funding cliffs across all states as we develop the next iteration of the formula. Ultimately, we want to help states address their needs.

QUESTIONS:

Q: Overdoses continue to skyrocket. Can you please explain what the State Opioid Response funds are used for and any accomplishments from last year?

- The SOR program provides funding to states and territories to implement strategies that prevent, intervene in, and promote recovery from issues related to opioid use and misuse and stimulant use.
- In FY 2022, SAMHSA awarded base State Opioid Response grants to 58 states and territories via a formula. The program includes a 15 percent set-aside for states with the highest mortality rate related to drug overdose deaths.
- Since the program began, states report that approximately 1,148,915 patients have received treatment services, including 553,347 who have received an FDA-approved medication for opioid use disorder.
- Through the program, 97,768 patients received treatment services for stimulant use disorder and 1,171,670 patients received recovery support services.
- It is also important to note that SAMHSA also provides Tribal Opioid Response grants through this program, which addresses the public health crisis of escalating opioid misuse and overdose in Tribal communities. In FY 2022, SAMHSA awarded \$55 million in TOR grants.
 - Since 2018, Tribes and Tribal organizations have provided TOR-funded treatment and recovery support services to 7,700 clients. Tribes have also purchased and distributed 16,955 naloxone kits and 7,045 fentanyl testing strips and trained 3,357 community members on the use of lifesaving naloxone.

Q: As you work to administer State Opioid Response grants this year, will you commit to working with me to ensure that small changes in a state's ranking in opioid overdose deaths do not result in large-scale reductions in funding?

- The State Opioid Response Grant program is a critical program helping states address the overdose epidemic. For the FY 2022 and FY 2023 SOR awards, SAMHSA held states harmless for pandemic-related factors and a data definitional change for substance use disorders that occurred in 2020.
- We understand the importance of avoiding funding cliffs across all states as we develop the next iteration of the formula. Ultimately, we want to help states address their needs.

Q. Fatal and non-fatal overdoses on Native American Reservations are typically higher, can you share any data on what the Tribal Opioid Response (TOR) grants were used for last year?

- In FY 2022, SAMSHA funded 102 new Tribal Opioid Response grants. Since 2018, Tribes and Tribal organizations have provided Tribal Opioid Response-funded treatment and recovery support services to 7,700 clients.
- Tribes have also purchased and distributed 16,955 naloxone kits and 7,045 fentanyl testing strips and trained 3,357 community members on the use of lifesaving naloxone.
- Tribes and Tribal organizations funded through TOR also educated over 25,000 individuals on the consequences of opioid misuse and overdose through prevention activities.

Surprise Billing

TALKING POINTS:

- I would like to start by again thanking Congress for its leadership in enacting this law to protect patients from surprise billing in health care. Patients and their families deserve the security of knowing they are kept out of the middle of disagreements between insurers and providers.
- HHS—together with our colleagues at the Department of Labor, Department of the Treasury, and Office of Personnel Management—has been working to implement the No Surprises Act and ensure that consumers receive the benefits of the protections included in the law by Congress.
- We are committed to continuing to protect patients from crippling medical bills and increase transparency in our health care system. That is why this Administration is requesting \$500 million to replenish and extend the No Surprises Act Implementation Fund.

Statistics on Disputes

- Between the April 15, 2022 launch of the Federal IDR portal and December 5, 2022, disputing parties initiated over 164,000 disputes. This case load is ten times greater than the Departments initially estimated there would be over the course of a full calendar year.
- Tens of thousands of these disputes have been found ineligible for the Federal IDR process.
- This situation has resulted in low collections of the administrative fee relative to the volume of disputes processed in the portal.

QUESTIONS:

Q: There is concern about the provider burden and impact of an increased administrative fee. Can you give additional detail on the methodology and rationale for the administrative fee increase?

- As you know, we released an initial public report on the Federal IDR process and an updated administrative fee guidance document for 2023. There are two big trends.
 1. First, there is a very high volume of disputes being submitted for resolution, significantly more than we or the IDR entities anticipated or were staffed for. For example, through December 5th of last year, there were over 160,000 disputes submitted through the portal.
 2. Second, IDR entities have had to perform a substantial amount of outreach and analysis to determine whether a dispute is eligible for the Federal IDR process.
- The high volume and complexity of this work was taking away from IDR entities' ability to review bona fide disputes and the structure of the No Surprises Act regulations prevents IDR entities from being compensated for cases that are not eligible.
- We've taken steps to help address some of the ongoing challenges created by the large initial volume of disputes to allow IDR to focus on making payment determinations,

including making sure the administrative fee covers “pre-eligibility” actions and setting that fee at a level that covers the estimated annual cost of operating the Federal IDR process and working on system changes and considering policy options that will allow us to reduce the IDR administrative fee in the future and make the process smoother for everyone.

Q: Why is the Administration requesting additional funds for No Surprises Act implementation?

- To implement the No Surprises Act, the Departments scaled up expertise and resources for rulemaking, technical builds, enforcement, and staffing.
- A one-time lump-sum appropriation of \$500 million was provided to the Departments for implementation of the No Surprises Act and Title II Transparency provisions.
- While the original appropriation expires at the end of 2024, most of the statutory requirements added by the No Surprises Act and Title II Transparency provisions are permanent and the Departments will have ongoing responsibilities such as enforcement of plan, issuer, and provider compliance; complaints collection and investigation; as well as auditing comparative analyses of non-quantitative treatment limits for mental health and substance-use disorder plan benefits.
- While some activities, particularly those around the Federal IDR process, are supported through a separate administrative fee, many other activities implementing the No Surprises Act are not.
- Factoring in cost projections for those activities that the Departments are currently undertaking, the Departments project that the No Surprises Act Implementation Fund will be exhausted before the end of calendar year 2024. The continued implementation of these provisions will have to compete against other agency priorities and initiatives, especially as funding for certain appropriations, such as for CMS Program Management, haven't kept pace with the increasing responsibilities that have been delegated to the agencies.

Q: A recent article suggests that there may be a loophole in the No Surprises Act allowing providers to remain out-of-network while contracting with plans as a ‘participating’ provider, thereby exposing patients to out-of-network coinsurances for services, including when they have not received notice or provided consent to those services or charges. What is HHS doing to evaluate this potential loophole and ensure that it is not impacting patients?

- Patients and their families deserve the security of knowing that their coverage will be there for them when they need it.
- With regards to the article suggesting a loophole in the NSA, we are continuing to look into this issue but don't have any updates at this time.
- Ultimately, we are committed to continuing to work to ensure that the law protects patients from surprise medical bills and we value your feedback as we do so.

NOTE: Senators Hassan, Cassidy, Murray and Sanders staff have asked for a briefing from HHS, DOL & Treasury on this issue.

If asked about this briefing....

I understand that we are still looking into this issue and that our staffs are in contact about setting up this briefing.

Q: With this increase in the Administrative fee, providers with small dollar claims are effectively shut out of the IDR process because the fees are more than they could win in an IDR case – did you consider provider access to IDR when you updated the administrative fee?

- We are required by statute to set the fee at an amount that is estimated to cover our costs of operating the Federal IDR process for the year.
- We believe that the fee increase was necessary, in light of the rising volume of disputes and the Departments' substantial pre-eligibility work to support IDR entities eligibility determinations - to address the significant backlog of disputes.
- While we are taking on this additional work to address the current issues, we are working on system changes and considering policy options, including rulemaking, to make the process smoother for everyone.

Q: How did you arrive at \$350? Can you give us the methodology for how fees increase 600%?

- The methodology used to determine the amount of the administrative fee – which is required by statute to cover the estimated costs associated with carrying out the IDR process, is described in an interim final rule (IFR) that we issued in September 2021. Specifically, the IFR described some of the types of costs that the Departments would consider in setting the fee.
- Consistent with this methodology, as we described in the December 2022 fee guidance, when we amended the fee, we relied on new data informed by the actual costs to establish the amended administrative fee.
- I'm limited in what I can say given ongoing litigation on this issue.

Q: I'm hearing from providers that they cannot get paid because the Administration paused all IDR determinations? When are IDR entities going to be allowed to resume payment determinations?

- Certified IDR entities have now resumed processing all payment determinations.

- We have posted notices about this issue on the CMS No Surprises Act webpage.
- The Departments have made guidance and system updates in order to ensure that certified IDR entities comply with the TMA II opinion and order when issuing payment determinations for disputes involving items or services furnished on or after October 25, 2022.
- I'd be happy to have my staff follow up with your office with details on these updates.

Q: We have heard from stakeholders that payments to the winning party in an IDR dispute are not being made in a timely manner in accordance with the requirements of the No Surprises Act. What is HHS doing to enforce the requirement that any payment owed by a health plan or provider as a result of an IDR decision is being made promptly?

- Our regulations require that the losing party remit payment within 30 days of a payment determination. If the prevailing party believes that the non-prevailing party isn't complying with the payment requirements with the dispute resolution process, then we encourage them to contact the No Surprises Help Desk to submit a complaint.
- We are investigating the complaints that we have received on this issue.

Q: Does CMS intend to release the findings of their Qualifying Payment Amount (QPA) audits, in addition to submitting a report on these audits to Congress as required by the No Surprises Act?

- We are conducting qualifying payment amount (QPA) audits to ensure that plans are complying with requirements related to its calculation and disclosure.
- The Departments are actively conducting QPA audits as required under the statute and intend to produce the reports to Congress required.

TANF

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Mandatory Program Funding	17.3B	17.3B	
Proposal Impact to TANF	-	5	5
Proposal Impact to TANF Contingency Fund	-	(5)	(5)
Total Program Level	17.3B	17.3B	-

TALKING POINTS:

- The Department shares your commitment to an effective safety net system that ensures funds are spent to accomplish a TANF purpose and welcomes the opportunity to work with you to strengthen TANF.
- TANF is intended to serve as a critical support to families experiencing economic hardships, providing cash assistance, employment and training assistance, and related services to ensure families can meet basic needs, get access to opportunities in the job market, and remain together; and we must strengthen the program so that it can meet its purposes and continue to support families and communities.
- We will continue to support all grantees in strengthening policies and practices that effectively invest in basic assistance and family supports with program integrity and accountability.
 - The Department is requesting new statutory authority in the TANF program to increase transparency with respect to TANF spending and implement program integrity measurement across the program.
 - Increased monitoring of TANF expenditures and their alignment with allowable uses of block grant funds are necessary to ensure that TANF functions as it was intended – as a critical support to families experiencing economic hardships, providing cash assistance, employment and training assistance, and related services so that families can meet basic needs, get access to opportunities in the job market, and remain together. ACF wants to collect data to improve monitoring of allowable uses of funds.
 - Congressional action is needed to equip the Department to fully implement additional program integrity measures. We welcome the Committee's partnership in supporting these requests.

QUESTIONS:

Q: Mississippi has been in the news for the large-scale conspiracy and embezzlement of millions of dollars in TANF funding involving the Mississippi Department of Human Services. How are largescale abuses like this happening under HHS' watch?

- As has been reported in the news media, multiple Federal and State agencies are continuing to review this case.
- While we are unable to share specifics on the ongoing assessment of misuse of funds in Mississippi, we do want to reaffirm our commitment to ensuring the highest degree of accountability and integrity within the TANF program nationally.

Q: What is the Department doing to recover taxpayer dollars?

- The Department will work to recover any misused TANF funds from the state. Federal law requires that a state replace with its own state funds any federal TANF funds subject to penalty because the funds were misused.
- When the Department has a complete assessment of the extent of the fraud and misuse, we intend to pursue all appropriate measures, including a TANF penalty, if warranted. The Department does not recover funds directly from individuals or a state's subgrantees.

Q: The Mississippi case demonstrates that state misuse of TANF funds is rampant. Can you speak to how the program has strayed from Congressional intent? Has HHS conducted a systematic review to identify areas of fiscal, administrative, or programmatic weaknesses in the TANF program?

- More than 26 years since TANF was established, state programs have shifted away from a focus on direct cash and employment assistance—services we know make the biggest impact on reducing family and child poverty and are reaching the fewest number of families since passage of welfare reform.
- At the same time, states are using TANF funds on a wide range of benefits and services that have tenuous connection to the statutory purposes of TANF and Congressional intent, including funding for activities without regard to the income or parental status of the recipient.
- HHS has limited oversight of state TANF programs. When possible, HHS uses existing tools to oversee the program, such as Single Audit Reports and other reporting mechanisms. HHS has conducted periodic improper payment risk assessments and works to address weaknesses identified as part of that process (as well as through other oversight mechanisms).
- We intend to pursue all options within our authority to ensure allowable expenses align with TANF purposes.

Q: Has HHS conducted a systematic review to identify areas of fiscal, administrative, or programmatic weaknesses in the TANF program?

- Due to statutory limitations on information that HHS is able to collect from states, the Single Audit report is a key oversight and monitoring tool for the TANF program. Single Audits assess if states have complied with program requirements for areas including

allowable activities, allowable costs, cash management, eligibility, reporting, period of availability of funds, procurement, and sub-recipient monitoring.

- ACF staff thoroughly review the Single Audit reports to determine the need to assess any TANF penalties, as required by statute, as well as to identify areas where states may need additional supports and technical assistance to remediate any weaknesses in internal controls.
- HHS has also completed a TANF improper payment risk assessment, which is used to identify areas of additional risk mitigation.

Q: Does the Department have processes in place to measure and report the amount of improper payments in the TANF program?

- Statutory limitations preclude HHS from collecting information needed to calculate and report a national TANF improper payment error rate.
- This constraint significantly limits ACF's ability to request data needed to calculate a national error rate.
- However, the proposal included in the FY 2024 President's Budget Request, if enacted, would allow ACF to collect data elements pertaining to a range of TANF expenditures, including subrecipient payments for benefits and services, and allow the agency to calculate and report a more robust national TANF error rate estimate.

Title 42

TALKING POINTS:

- Title 42 permits the Director of the CDC to prohibit the introduction of persons when there is serious danger of the introduction of a communicable disease into the United States—and also to aid in continued efforts to mitigate spread of that disease.
- Based on the latest public health information at the time, CDC terminated all Title 42 orders in April 2022.
- However, as you know, the Title 42 Order remains in place due to court order.
- The public health system whether through Title 42 or any other measure is not a replacement for meaningful immigration reform, and it is incumbent upon Congress to come together and find a comprehensive solution.

QUESTIONS:

[Defer questions on DHS readiness to DHS]

Why is the Department not using Title 42 to stop Fentanyl from coming across the border?

- The authority under Title 42 is rooted in protecting public health in regard to communicable disease.
- While the public health emergency for the opioid crisis is ongoing and we have grave concerns about the increase in overdoses, drug interdiction, drug trafficking, and drug use are outside the scope of Title 42.

Tobacco

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Tobacco User Fees	712	812	+100

TALKING POINTS:

- HHS and FDA are laser focused on protecting children from the harms of tobacco use. Since 2019, e-cigarette use among youth has been **reduced by almost 50 percent**.
- FDA has taken significant enforcement actions against e-cigarette companies in the last year, issuing taken action on **99% of the 26 million** e-cigarette product applications. FDA has issued over **1.2 million market denial orders**, and for the first time ever issued civil monetary penalties against e-cigarette companies in violation of the law.
- The Budget provides \$780 million in tobacco user fees to invest in product review and evaluation, research, compliance and enforcement, public education campaigns, and policy development.
- To enhance the regulation of these products and to better protect our children, the budget proposes an additional **\$100 million** in tobacco **user fees**, and provides FDA with the authority to assess user fees from manufacturers and importers of all deemed products.
- This investment will support **Center for Tobacco Product's five-year strategic plan** and comprehensive policy agenda; optimize the application review framework; support additional action to remove illegal products from the market; and enhance public communications and transparency around our work.

QUESTIONS:

Q: How will FDA improve consistent regulation of the tobacco industry?

- We've made important progress and reached science-based regulatory decisions across a broad array of products in the 13 years since Congress tasked the FDA with regulating tobacco products.
- And yet, while the current cigarette smoking rate is the lowest in history, we are faced with significant challenges because of the evolving use of tobacco products, especially in the e-cigarette industry.
- FDA plans to release a five-year strategic plan and comprehensive policy agenda; optimize the application review framework; take additional action to remove illegal products from the market; and enhance public communications and transparency around our work.

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- It's imperative that we are able to meaningfully implement transformational regulations and make decisions based on the public health standard in the law, with the American public – not the interests of the tobacco industry – at the forefront.
- These efforts could be bolstered by the budget proposal to increase user fee collections by \$100 million, which ensure all manufacturers support appropriate regulation of tobacco products.

Topic: Rural Emergency Hospitals (REHs)

TALKING POINTS:

- Thanks to Congress's leadership in the Consolidated Appropriations Act of 2021, CMS has implemented a new Medicare provider type, the Rural Emergency Hospital, to address the growing concern over closures of rural hospitals.
- Applications are available now for hospitals in rural areas that would like to change to this new provider type.
- The REH designation provides an opportunity for Critical Access Hospitals and certain rural hospitals that generally do not provide acute care inpatient services to avert potential closure.
- By converting to an REH, eligible rural facilities are able to provide emergency services, observation care, and additional medical and health outpatient services.
- In January 2023, CMS issued guidance regarding the REH enrollment and conversion process for eligible facilities. Some hospitals have already converted to this new provider type in 2023.

UC - Contracts for Border Services/Facilities

TALKING POINTS:

- When it comes to contracts for border services and facilities, ORR operates under the same child welfare principals that guide its core mission. Safety and well-being are at the forefront of every decision we make at HHS.
- In FY 2021, ORR faced a dramatic increase in referrals of Unaccompanied Children. Due to the need to urgently increase ORR's capacity to protect the tens of thousands of children in its care in the face of exceptional circumstances, HHS employed contracting authorities that allow federal agencies to limit competition in certain urgent circumstances.
- This was designed to avoid unacceptable delays in fulfilling ORR's need to expand its bed capacity, including by standing up emergency intake sites (EIS), to protect the safety and well-being of the children in its care.
- Through improvements in case management services across the network, increased staffing, and success of COVID-19 mitigation measures, by spring 2022, ORR was able to open back up standard network capacity, which made reliance on EIS less necessary.

QUESTIONS:

Q: HHS has awarded Family Endeavors, Inc. more than \$1 billion to provide certain facilities and services for the UC program. These contracts were not competitively awarded, and they went to a company that months earlier had hired an individual who served on President Biden's transition team. Do you think it's acceptable to award taxpayer dollars based on political support like this?

- The contracts issued to Family Endeavors were awarded under contracting authorities that allow federal agencies to limit competition in certain circumstances.
- The authorities HHS used included awarding contracts based on unusual and compelling urgency and the identification of only one responsible source—in order to avoid unacceptable delays in fulfilling ORR's need to expand its bed capacity in the face of urgent circumstances.
- I understand that the OIG is currently conducting an audit of an HHS contract award to Family Endeavors. HHS recognizes and respects the OIG's authority to conduct independent audits, and we will continue to cooperate fully with the OIG.

UC - Ft. Bliss OIG Report

TALKING POINTS:

- In 2021, ORR received an unprecedented number of UC referrals during the middle of the pandemic, straining its bed capacity and also its ability quickly recruit and staff programs across the country. As ORR worked quickly to respond to this unprecedented emergency, with limited resources, it prioritized the safety and wellbeing of children at every step. Despite challenges, and lessons learned, Fort Bliss now is a model for child centered care and case management.
- ORR continues to build capacity that enhances our ability to manage emergency response efforts by expanding bed capacity, minimizing the amount of time children stay in congregate care settings, and safely placing children with vetted sponsors. Additionally, ACF has worked to increase staff training, supports and whistleblower protections to continue to provide the safest environment possible for children.
- ACF and ORR took seriously the findings of the OIG report and had already started implementing its recommendations even before it was published. Today, the reality at ICFs like Fort Bliss and Pecos is vastly different from the snapshot that the OIG report captured during the surge – bed capacity is at a record high, and time in care for children has decreased dramatically.

UC - HHS/DOL Child Labor

TALKING POINTS:

- The New York Times article demonstrates the terrible ways that employers are exploiting the economic situation that many children and families in the United States find themselves in, including children who have previously been in ORR care.
 - The previous administration left us a number of challenges to fix, and not least among them at HHS was the rebuilding of ORR and the Unaccompanied Children's Program in the face of unprecedented referrals in the midst of a global pandemic.
- We take the issue of child labor very seriously, and there are additional steps that we can take to educate children and our providers about child labor exploitation, ensure sponsors understand the hazards of child labor, and collaborate with the Department of Labor to do everything we can to reduce the likelihood that children will end up in a situation where they are exploited.
 - Of course, we always look for ways we can do better. That's why are we auditing our program to see if there's any place where we can tighten up our processes.
- Our principal responsibility is to care for unaccompanied children while they are in our custody, and then make sure we can place the child to a safe, vetted sponsor. HHS looks forward to partnering with you to advance the shared mission of protecting children and continue to strengthen the quality and depth of services we offer.

QUESTIONS:

Q: When it comes to vetting sponsors, why did HHS pair down fingerprinting and case reviews?

- First, let me start with HHS prioritizes the safety and wellbeing of every child in our care. All decisions by HHS are done with this in mind. We thoroughly vet every sponsor before placing a child in their care.
- HHS has not changed any vetting protections that would affect the safety of children in our care. In 2021, ORR received an unprecedented number of UC referrals. ORR ***did not make policy changes*** that cut out safety measures or accelerated processes that might ***put children at risk***.
- It is particularly important to prioritize timely placement with biological parents or legal guardians. This is why we updated our process when we came into office – when it comes to placing a child with their parent (or legal guardian), **we cut through the red tape** in accordance with their parental right to be unified with their children as soon as possible. We heard from advocates and stakeholders, reviewed our process, and were able to make these improvements.

- ORR has and continues to work to keep children out of large, congregate settings without sacrificing procedures that keeps them safe.

Q: Does HHS have room for improvement?

- We continuously review our policies and procedures for ways to be more efficient and effective.
- Research shows children do much better with their families and in home settings, not government funded congregate settings.
- If a safe, vetted sponsor is available, we will not delay doing what is best for the child.

Q: How does ORR check on a child's wellbeing after they are placed with a sponsor?

- While ORR's custodial responsibilities for unaccompanied children end when the child is released from ORR care, ORR engages in a range of post-release activities and assists in supporting access to such services for children and sponsors.
- We all recognize how heartbreaking the situation is, and the challenges these children face – this calls for a whole of government response (including state government, local government, and community groups), and HHS takes our part in this continuum of care seriously.
- ORR's post-release services include assistance in connecting children and their sponsors to community-based resources suitable to their needs, and support to prevent a child from becoming a victim of trafficking.

Q: The article had recordings of you that implied you were prioritizing speed of discharges over child safety. Did the pressure of the UC surge cause HHS to sacrifice standards?

- The larger context of that quote was not captured – of course my priority and the Department's priority is to keep kids safe no matter what.
- The Department does not want children to be kept in large, congregate settings unnecessarily when a safe, vetted sponsor is available. That's both our legal and moral obligation.
 - When I made those comments, we were seeing inconsistency from week to week and wanted to improve the process while continuing to provide child-centered care for children in our custody until they were released to a thoroughly vetted sponsor.
- Last summer, there was limited space and facilities to care for children, and we needed to ensure we were being efficient – not just on one day, but every day – when it came to placing the children in our care with a safe and vetted sponsor.

Q: Recent reporting shows that there has been an increase in children being released to sponsors that are not family. Is HHS prioritizing a quick release of a child over a safer release to a family member?

- That data is not accurate. In FY 2022, 85% of children were released to their immediate or extended family. In FY 2022, 34.8% of children were released to their parents, and we continue to see an increase of unaccompanied children released to their parents. Thus far, in FY 2023, 37.3% of children have been released to their parents.

Q: Are children being sent to live with strangers?

- No. While a preexisting relationship is not required for an unaccompanied child to be released to a sponsor, ORR takes this into account when determining the suitability of the case for release and may require that the sponsor, the unaccompanied child, and the child's family, establish ongoing regular contact while the child is in ORR care prior to a release recommendations. Such releases, however, are rare.

Q: Advocates are calling for more legal services. They say that HHS is sitting on money that it could use for these services. What's your response?

- HHS has already expanded legal and post release services to historic levels and has been working to expand access to these services for all children who come through ORR care – doubling the number of children and families receiving post-release services since President Biden took office.
- We will continue to work with Congress to expand post-release services to all children by 2025 and we will continue to work with advocacy organizations to build additional legal capacity that can support our goal of providing full legal services.

Q: How, if at all, does HHS coordinate with other agencies and departments, including the Department of Labor, the Department of Justice, and others, to identify and reduce child labor exploitation, including among unaccompanied children?

- As mentioned, ORR must refer any trafficking concerns to DHS to investigate any trafficking claims.
- ORR and all its network of care providers must also refer any suspected trafficking case to the Office of Trafficking in Persons (OTIP). All cases referred to OTIP are reviewed to assess trafficking concerns and connect the minors to benefits and services.

UC - ORR/Migrant Flights

TALKING POINTS:

- This is an issue where misinformation has run rampant, and I want to set the record straight. It is our legal responsibility to provide safe, appropriate care to unaccompanied migrant children during the time they are in our custody, and that includes transportation to appropriate shelter placements and to unify with their vetted sponsors while they await immigration proceedings.
- There are no secret flights. And these flights are different and unrelated to the ones folks may have heard about on the news, such as the flights of migrant families to Martha's Vineyard. These flights to transfer UCs to their sponsors or to our network of over 200 shelter facilities in 22 states take place in accordance with the law and our responsibilities.
- Staff supervise and escort UC until they are placed in the care of another ORR facility or a vetted family member or sponsor. This has been the policy across multiple administrations since 2014. Transportation is coordinated, and clearly communicated to all appropriate parties, from a secure ORR facility to a vetted family member or sponsor or other ORR facility that is ready and awaiting the arrival of the UC. Through case management services, UC are always aware of where they are going and why.

UC - Reproductive Health

TALKING POINTS:

- ORR has a moral and legal obligation to safely and humanely care for all unaccompanied children referred to us. HHS works with our partners across the government to ensure that unaccompanied children are safe and provided – in accordance with the Flores Settlement Agreement and *Garza* – appropriate routine medical care, family planning services, access to reproductive health services, and emergency contraception and health care services.
- The Department's priority is to ensure that the populations we serve receive the reproductive care they need while following applicable legal requirements. ORR decision making is rooted in an ongoing assessment of the best interests of the child and established child welfare best practices.
- We remain committed to clearly explaining the care available and providing referrals or arranging appointments with healthcare providers which may include arranging and funding travel from states where laws may restrict care to states where necessary care is available.

QUESTIONS:

Q: What reproductive services are available to minors in ORR care?

- While in ORR care and custody, UC have access to family planning services and reproductive health care. Services include: pregnancy testing, emergency contraception, and comprehensive information about and access to reproductive health services. ORR also ensures access to oral contraceptive pills that are prescribed by a healthcare provider for a medically indicated diagnosis. ORR ensures that pregnant UC receive non-directive pregnancy options counseling when necessary and that appropriate specialty care referrals are made as soon as UC is discovered to be pregnant for further evaluation and care.

Q: What policies does ORR follow in regard to abortion?

- The UC program and its policies are aligned with the Flores Settlement Agreement, the Homeland Security Act, the Trafficking Victims Protection Reauthorization Act, and the ORR Policy Guide. ORR care providers are also typically state-licensed and therefore must abide by the healthcare requirements applicable in each relevant state.

Q: How does ORR protect the first amendment rights of federal staff and care provider staff who have personal/faith-based objection to abortion?

- Nothing in existing *Garza* policy prohibits ORR from providing accommodations to care providers who maintain a sincerely held religious objection to abortion; rather ORR does provide such accommodations.
- If a faith-based care provider has a religious objection to abortion, and a UC in the care of such a provider is discovered to be pregnant, ORR's field staff will personally deliver any legally required notice to the UC orally and in writing, along with other pregnancy-related information required by ORR policy.

- Faith-based providers are critical partners for our mission. ORR operates 102 different faith-based providers in at least 18 states.

Q: What if UC in care does not want an abortion? What care is provided to them?

- ORR is required to provide pregnant UC non-directive options counseling. UC are notified that neither the federal government, nor care providers, may obstruct or interfere with UC accessing counseling about all the options they have regarding their pregnancy.
- UC in ORR care can decide whether to continue their pregnancy or terminate the pregnancy.

Q: How many pregnant UCs have given birth (and kept) their babies? How many UCs have requested abortion since the passing of the Dobbs decision? How many abortions does ORR pay for each year?

- ORR does not disclose this information to protect children's medical and health privacy, especially given that this is a very small number.

Q: What about the Hyde Amendment? How are federal funds being used to provide abortions for UC?

- Nothing in the ORR Garza policy supersedes applicable Federal appropriations restrictions such as those outlined in the Hyde Amendment.

Q: Does the government pay for transportation of UC across state lines to access abortion services? Is this true for Hyde Amendment and non-Hyde Amendment abortions?

- ORR regularly facilitates access to medical services for UC, including transporting UC across state lines, when necessary. The care provider is responsible for transporting the UC to medical appointments, including access to reproductive health care across state lines. Where a religious exemption is in place, ORR staff may assist with the transportation of the UC to seek abortion services.

Q: Does the government pay for lodging, translation, and other ancillary services, in the course of facilitating access to abortion services? Is this true for Hyde Amendment and non-Hyde Amendment abortions?

- Yes, the government may fund lodging, translation, and other ancillary services in the course of facilitating access to abortion, regardless of whether the pregnancy meets the Hyde Amendment specifications or not. Care providers and child advocates may receive donations to help pay for some of these expenses on an as-needed basis.

Q: Does ORR prohibit access to abortion past a certain gestation ("late-term pregnancy")?

- ORR federal staff and care provider staff will assist in facilitating an abortion request by a UC, based on the available in consultation with DHUC, in compliance with *Garza* requirements and the Hyde Amendment. The time limit for an abortion procedure prescribed to the UC is in the purview of the medical provider and the UC and is not the purview of ORR.

UC - Sponsor Vetting/Post-Release Services

TALKING POINTS:

- Safety and well-being are at the forefront of every decision we make at HHS. Child welfare best practices are clear that the best place for a child is in a community with family and not in large congregate care settings. Once we identify a safe, vetted sponsor, who has undergone a robust screening process, we have a responsibility to place the child as quickly as possible.
- We also understand the importance of providing children and sponsors with the tools and resources necessary to help a child succeed post-release and develop permanent connections for support and resilience as a child transition into a new community.
- HHS has already expanded legal and post release services to historic levels and has been working to expand access to these services for all children who come through ORR care – doubling the number of children and families receiving post-release services since President Biden took office.
- HHS will continue to work with Congress to ensure we have the funding to build on this expansion of post-release services with the goal of serving all children within the next two years. It will also continue to evaluate pathways to strengthen

QUESTIONS:

Q: When it comes to vetting sponsors, why did HHS pair down fingerprinting and case reviews?

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Q: How does ORR check on a child's wellbeing after they are placed with a sponsor?

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- We all recognize how heartbreaking the situation is, and the challenges these children face – this calls for a whole of government response (including state government, local government, and community groups), and HHS takes our part in this continuum of care seriously.
- ORR's post-release services include assistance in connecting children and their sponsors to community-based resources suitable to their needs, and support to prevent a child from becoming a victim of trafficking.

Q: Recent reporting shows that there has been an increase in children being released to sponsors that are not family. Is HHS prioritizing a quick release of a child over a safer release to a family member?

- That data is not accurate. In FY 2022, 85% of children were released to their immediate or extended family. In FY 2023, 34.8% of children were released to their parents, and we continue to see an increase of unaccompanied children released to their parents. Thus far, in FY 2024, 37.3% of children have been released to their parents.

Q: Are children being sent to live with strangers?

- No. While a preexisting relationship is not required for an unaccompanied child to be released to a sponsor, ORR takes this into account when determining the suitability of the case for release and may require that the sponsor, the unaccompanied child, and the child's family, establish ongoing regular contact while the child is in ORR care prior to a release recommendations. Such releases, however, are rare.

Q: What exactly is the process for vetting sponsors?

- The process includes a proactive search by the care provider for a potential sponsor; a written sponsor application; interviews; required documentation establishing sponsor identity, address, relationship to the child, and other supporting documentation; background checks; and home studies as required by law and in ORR's discretion consistent with its policies.
- ORR thoroughly screens sponsors through tools that may include public records checks, sex offender registry checks, and fingerprinting.

Q: Why would numerous unaccompanied children be released to the same address?

- There might be various reasons why several children are released to sponsors at the same address including a large apartment complex or other address with multiple units. ORR has systems in place that alert users when sponsors are concurrently sponsoring other

children or have sponsored other children in the past. If ORR records show that multiple children are being released to the same address, ORR might conduct additional checks, such as requiring home studies before releasing other UC to those locations.

UC - Transgender Care

TALKING POINTS:

- ORR has a moral and legal obligation to safely and humanely care for all unaccompanied children referred to us. That means that *all* children and youth in ORR care are entitled to human rights protections and freedom from discrimination and abuse, no matter their gender or sexuality.
- Care providers must ensure that LGBTQI children are fairly treated and served and are not discriminated against during their time in ORR care. That means in part that they must maintain privacy and confidentiality of information concerning sexual orientation and gender identity. They need to use correct names and pronouns in accordance with the youth's gender identity. They must house LGBTQI youth according to an assessment of the youth's gender identity and housing preference, health and safety needs, and State and local licensing standards.
- While we have a guide for provider obligations with respect to LGBTQI children and youth in ORR care, ORR does not currently have any other policy on access to gender-affirming care. Faith-based providers are critical partners for our mission. ORR does not have specific policy concerning faith-based grantees and care for transgender UCs. This is a new policy area for ORR, and we continue to study the issue for policy development.

QUESTIONS:

Q: Does ORR provide gender-altering healthcare to UC at their request? Are there examples of this happening?

- UC Policy Guide 3.5 outlines care provider obligations with respect to LGBTQI children and youth in ORR care. The ORR UC Program does not currently have any other policy on access to gender-affirming care.

Q: Does ORR allow for male children to reside in female residential areas and utilize female restrooms just because they say so?

- To provide the least restrictive placement suitable for each child and ensure the safety and wellbeing of children in care, ORR considers all available information when making placement decisions, including the child's identity documents, physical anatomy, and self-identification of their gender and safety needs when determining the child's housing and service allocation.
- Care providers must offer an individualized assessment to determine whether additional or alternate restroom accommodations should be provided. UC are always supervised and ORR's priority is the safety of all children in its care.

Q: What is a woman?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.

- Support youth and families; HHS commitment to advance safety and support for LGBTI+ youth. Access to gender affirming care, when medically necessary can be lifesaving.
 - Ensuring such access is the law.

Q: How many genders are there?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- At HHS, we are committed to advancing health equity for people of all genders. Health equity is defined by HHS Healthy People 2030 as the “attainment of the highest quality of health for all people.” We work toward that goal every day.

Q: Does HHS support irreversible genital surgeries on children?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

Q: What other requirements are providers supposed to adhere to in regard to LGBTQI children?

- They must maintain privacy and confidentiality of information concerning sexual orientation and gender identity.
- They need to use correct names and pronouns in accordance with the youth's gender identity. They must house LGBTQI youth according to an assessment of the youth's gender identity and housing preference, health and safety needs, and State and local licensing standards.
- They must offer an individualized assessment to determine whether additional or alternate restroom accommodations should be provided.
- They must allow LGBTQI youth to dress and express themselves according to their gender identity.
- They must allow LGBTQI youth to choose the gender of staff to conduct a pat-down search if one is necessary.

UC - Violent/Criminal Former UCs

TALKING POINTS:

- This administration takes all cases of violent crime seriously, no matter the immigration status of the alleged criminal, or whether the individual was formerly in the custody of ORR care. While we remain committed to working with Congress to comprehensively fix the problems of a long-broken immigration system, ORR is not an immigration enforcement entity. It is ORR's legal responsibility to provide a safe environment for all children in its care.
- Since 2019, ORR has made significant improvements to assess and address its network capacity to better serve the needs of children with mental health and behavioral issues, including seeking and coordinating increased mental health and treatment services for shelter cases needing specialized placement.
- While ORR's custodial responsibilities for unaccompanied children end when the child is released from ORR care, ORR engages in a range of post-release activities and assists in supporting access to such services for children and sponsors. We have been building capacity to increase post release services and we are on track this year to serve more than 50% of children released from our care.
 - HHS will continue to work with Congress to ensure we have the funding to build on this expansion of post-release services with the goal of serving all children within the next two years.

QUESTIONS:

Q: The Biden Administration's open-border policies created vulnerabilities that criminals and gang members exploit. What is the Department doing

- Refer to CBP and DHS for specific questions on immigration policy. Again, ORR is not an immigration enforcement or law enforcement entity.

Q: What is HHS doing to verify whether UCs referred to their care are members of MS-13 or other violent gangs?

- HHS is required to ensure the safety and care of all unaccompanied children in ORR custody. Pursuant to the Trafficking Victims Protection Reauthorization Act, ORR is required to provide safe and secure placement for children. In addition, the *Flores* Settlement Agreement also outlines factors HHS must consider when ORR is making placement determinations, such as screenings for self-harm, harm to others, and flight risk. These requirements are reflected in ORR's UC Program Policy Guide (Section 1.2.4).
- HHS does not have the authority to conduct background checks on unaccompanied children. Prior to the Department of Homeland Security referring children to ORR custody, DHS fingerprints all children over the age of 14, and if there is criminal history based on those biometrics, these are reported to ORR as obligated under the 2021 HHS

and DHS Memorandum of Agreement. This MOA creates an affirmative obligation for DHS to provide the criminal history, gang affiliation, court docs, etc. for an unaccompanied child upon their referral to HHS. If made aware of additional DHS documents or court records, ORR will also seek these records.

Q: There have been reports that there has been a rise in missing unaccompanied children across the country. Is ORR tracking these children after release?

- Though ORR does not have custody of children after they are discharged, ORR provides safety and wellbeing calls to all children, and post-release services and legal representation to many children. ORR cannot compel former unaccompanied children or sponsors to respond to inquiries or participate in these services. There are many reasons why discharged unaccompanied children, who often live in mixed-immigration-status families, may not want to be contacted by the U.S. government.

Vulnerable Children + Youth

(Dollars in Millions)

Discretionary Funding	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Runaway & Homeless Youth	146	159	+13
Child Abuse Programs	214	257	+43
Child Welfare Programs	339	431	+92
Adoption Incentives	75	75	-
Family Violence Prevention Services	261	519	+259
Total Vulnerable Populations Program Level	1,226	1,683	+457

TALKING POINTS:

- It is the Department's responsibility to protect those most vulnerable among us – and that means making robust investments in care settings and supports for children in the foster care system, investments in children and youth in at-risk situations, and investments in family violence and child abuse prevention programs.
- This Administration is delivering on that mission with its FY24 budget, which increases funding for vulnerable populations across the board. To start, this budget nearly doubles funding for Family Violence Prevention Services Programs from last year's enacted levels.

- HHS is also committed to reducing child abuse and providing families with the support they need to remain safely together to avoid the trauma that results when children are placed in out-of-home-care – that's why we asked for a \$135 million increase to continue to support child welfare.
- These issues have historically had bipartisan consensus. The Department looks forward to continuing to partner with Congress to advance a child-centered and family-centered social service infrastructure.

QUESTIONS:

Q: We just marked 5 years since the bipartisan passage of the Family First Act – can you speak to how implementation is going across the country?

- The Family First Prevention Services Act (FFPSA) and its title IV-E prevention services program provides a watershed opportunity to create more equitable outcomes for children, youth, and families before they face the tumult and devastating consequences of maltreatment and separation.
- ACF estimates that 6,200 children were served by title IV-E prevention services programs in FY 2022, and, as more and more prevention programs are implemented, 672,500 children will be served annually by FY 2033
- We have seen great progress around the country among jurisdictions who have developed prevention plans under Family First to expand the in-home parenting skills programs, mental health programs, and substance use prevention and treatment programs in their communities.

Q: Family members are often an important part of our child welfare system, keeping kids safe, and keeping families together. What is the Administration doing to ensure that family members caring for children have the supports they need?

- When parents are unable to safely care for their own children, it is often grandparents, other family members, or kin who step forward to provide a loving home for those children, either temporarily or permanently. Research is clear that children in kinship care often experience less trauma and have better outcomes across a range of behavioral and developmental well-being measures.
- While kinship caregivers provide essential care to children, they often do not receive adequate support.
- The Biden-Harris Administration is committed to strengthening support for grandparents and other kin caring for children by working with states to ensure equitable access to licensure for relative foster care providers and by expanding services, resources and supports for kinship caregivers and the children in their care.
- The President's FY 2024 budget includes proposals to encourage placing children with relatives or kin when they cannot remain safely at home with parents.
- The President's FY 2024 budget also proposes to increase support for kinship navigator programs.

World Health Organization (WHO)

TALKING POINTS:

- We know that the challenges we face won't be solved by one leader or one country alone, but by the world coming together and fighting for what's right.
- The WHO is an essential organization; they are the only international organization with the mandate and convening power to bring together Ministries of Health and health experts across 194 countries.
- I strongly support the ongoing efforts to strengthen the WHO and make it more agile, transparent, efficient, and accountable.

QUESTIONS:

Q: Do you commit to voting against any reform in the Pandemic Accord or to the IHR that would violate the United States' sovereignty?

- The United States will not support any measure at the World Health Organization, including in these negotiations, that in any way undermines our sovereignty or security.
- Any accord resulting from these negotiations would be designed to increase the transparency and effectiveness of cooperation among nations during global pandemics and would in no way empower the WHO or any other international body to impose, direct, or oversee national actions.
- It will not compromise the ability of American citizens to make their own health care decisions.

Q: What steps will you take to ensure WHO adequately responds to allegations of widespread sexual abuse and exploitation?

- There must be zero tolerance for sexual exploitation and abuse at the WHO.
- HHS, State, and USAID have been working closely with the WHO as they respond to sexual exploitation and abuse allegations and work to build stronger systems to prevent and address this in the future.
- The WHO has made improvements and laid out a Management Response Plan with next steps to continue progress, but our pressure on these issues must continue to be a top priority.

Q: Do you support obligating the United States via international agreement to provide reproductive health services, including abortion, as essential health care during a pandemic?

- I will comply with all legislative restrictions on foreign assistance related to abortion, including restrictions against advocating for or against abortion in multilateral fora.

Q: It was recently reported that WHO was abandoning its investigation into the origins of the coronavirus. Do you think now is the time for international organizations like WHO to give in to China's obstruction and give up on this investigation?

- No. For more than two years, China has blocked international investigators and members of the global public health community from accessing information related to COVID-19 origins. This is unacceptable – and we must not let this prevent us from getting answers.
- If we're going to get to the bottom of this question, we need critical information about the origins of this pandemic that exists in the People's Republic of China.
- International investigators and members of the global public health community should have access to it.

Workforce – Head Start / Child Care

TALKING POINTS:

Head Start cannot fulfill its mission to serve children and families from vulnerable communities without a robust, well supported workforce.

- Head Start preschool teachers earn drastically less than kindergarten teachers with the same credentials, which limits a program's ability to recruit and retain staff.
- The budget would provide a much-needed investment to stabilize the workforce, including \$440 million for a cost-of-living adjustment for Head Start wages to keep pace with inflation. The budget also directs \$575 million to improve compensation for Head Start workers.
- We continue to explore how federal policy can better support the Head Start and child care workforce, as well as how to leverage opportunities available from partners at the local, state, and federal levels.

Background:

- The budget requests \$13.1 billion, an increase of \$1.1 billion above FY 2023 enacted, to provide comprehensive early learning and development services to infants, toddlers, and preschool-aged children from economically disadvantaged families. This funding includes \$440 million for a cost-of-living adjustment for Head Start wages to keep pace with inflation. The budget also directs \$575 million to improve compensation for Head Start workers. This investment reflects the Administration's priority of building and retaining a strong early childhood education workforce. The Administration continues to invest \$100 million in Early Head Start-Child Care. Partnerships. The partnership's funding provides comprehensive and continuous Early Head Start and child care services to low-income families with infants and toddlers. These investments will serve an estimated 813,573 children and families through nearly 1,600 local agencies in states, territories, and tribes across the United States.

Workforce - Health Care

TALKING POINTS:

- The need for a strong and robust healthcare workforce could not have been more apparent than during the height of the COVID-19 pandemic.
- We must continue to invest robustly in training, ongoing education, and mental well-being of our health care workforce.
- HHS has invested hundreds of millions of dollars in the health care workforce over the past year.
 - Over the next 5 years, we will create 1,000 new Graduate Medical Education (GME) slots. The first 200 GME slots were created at the beginning of 2023. Specifically focused on primary and mental health care providers.
 - We've invested \$103 million to provide resources to support health care workers and prevent burnout.
 - The National Health Service Corps is at its largest field strength, over 20,000 members, serving at more than 9,000 community health care centers seeing more than 21 million patients.
 - Awarded \$225 million to train 13,000 community health workers to strengthen the public health care workforce to prepare for future public health threats.
- The President's Budget for FY 2024 seeks to extend and expand funding for these programs to ensure that recent gains and funding capacity on these programs is not lost.

QUESTIONS:

Q: How does the Budget increase and strengthen the health workforce in response to health workforce shortages?

- The FY 24 Budget has several initiatives that will grow, diversify, and promote the well-being of the health workforce. The Budget proposes to:
 - Extend and increase mandatory funding for National Health Service Corps and Teaching Health Center Graduate Medical Education for 3 years through FY 2026.
 - Provide scholarships and loan repayment to clinicians in return for practicing in underserved areas and support over 20,000 providers (National Health Service Corps, \$965.6 million, an increase of \$547.7 million).
 - Funds over 1,400 primary care physicians and dental residents in community-based training (Teaching Health Center Graduate Medical Education, \$157 million, an increase of \$37.7 million).
 - Train Certified Nurse Midwives and to expand and modernize nursing education programs by increasing nurse faculty (\$349.9 Million, an increase of \$49.5 million, for the nursing workforce).
 - Train 18,000 more mental health and SUD providers (\$387.4 million, an increase of \$190.3 million, for Behavioral Health Workforce Development Programs).

- Seed new approaches with a new Health Care Innovation Workforce program to grow the health care workforce and address shortages (\$27.5 million).
- Expand the diversity of the health professions workforce (\$110.2 million, an increase of \$10.7 million).
- Support the behavioral health, and well-being of health care providers (\$25 million).

Q: If the NHSC received all of the funding requested in the President's Budget, will it eliminate workforce shortages? What would you need to close out the primary care shortages?

- The Budget would sustain and expand the record number of providers currently providing care or getting trained to serve in underserved and rural communities.
- Eliminating larger provider shortages would require a broader approach to build the pipeline, expand training capacity, and provide incentives for providers to go into communities with shortages, as well as increasing the number of other health care providers that comprise the care team, such as nurses, physician assistants, medical assistants, lab technicians and others.

Q: What are the consequences of not extending mandatory funding for the Teaching Health Center Graduate Medical Education Program?

- If funding is not received, hundreds of medical residents currently being trained in community-based settings could face interruption or termination of their residency programs.
- Without renewed funding, Teaching Health Centers may reduce the number of available training slots and some programs may close entirely.

Workforce - Mental Health

TALKING POINTS:

- HHS is committed to strengthening and expanding the workforce to respond to the mental health and substance use disorder crisis.
- We've been hard at work – working with Congress we've created new Graduate Medical Education slots, invested in resources to prevent burnout, funded training of community health workers, and more.
- But much more can and should be done. That is why the budget invests in the **behavioral health workforce** by supporting an estimated 27,000 total mental health and substance use disorder trainees and providers.
- Specifically, the budget proposes \$387 million for Behavioral Health Training Programs, an increase of +\$190 million, to grow the number of behavioral health professionals through training approximately 18,000 behavioral health providers; such as psychiatrists, psychologists, clinical social workers, marriage and family therapists, counselors, and peer support specialists.

QUESTIONS:

Q: What has HHS done to expand the mental health workforce?

- Working with Congress, HHS has invested **hundreds of millions of dollars** in the health care workforce over the past year.
 - Over the next 5 years, we will create **1,000 new Graduate Medical Education (GME) slots**. The first 200 GME slots were created at the beginning of 2023. Specifically focused on primary and mental health care providers. An additional 200 GME slots were added by CAA 2023, with 100 dedicated to psychiatry or psychiatry subspecialty residency positions.
 - We've invested **\$103 million** to provide resources to support health care workers and **prevent burnout**.
 - The National Health Service Corps is at its largest field strength, over **20,000 members**, serving at more than **9,000 community health care centers** seeing more than **21 million patients**.
 - Awarded **\$225 million** to train **13,000 community health workers** to strengthen the public health care workforce to prepare for future public health threats.
 - Next year, Medicare will finally **provide payment to care provided by therapists and Licensed Professional Counselors**.

Q: What else do you think needs to be done to expand the workforce?

- The FY 24 Budget has several initiatives that will grow, diversify, and strengthen the mental health workforce. The Budget proposes to:
 - Train 18,000 more mental health and SUD providers (\$387.4 million, an increase of \$190.3 million, for Behavioral Health Workforce Development Programs).

- Provide scholarships and loan repayment to clinicians in return for practicing in underserved areas and support over 20,000 providers (National Health Service Corps, \$965.6 million, an increase of \$547.7 million). The NHSC supports primary care medical, dental, and behavioral health providers through scholarships and loan repayment programs.
- Allocate \$37 million for the Minority Fellowship Program (MFP) to almost double the number of fellows in FY 2024. The budget also proposes to add a service requirement to ensure participants are supporting communities in need, as well as to add addiction medicine, and sexual and gender minority populations as participants in the program. .
- Allow Medicare to designate additional professionals such as clinical social workers, peer support workers, and certified addiction counselors to furnish behavioral health services within their applicable state licensure or scope of practice – the proposal builds CAA 2023's coverage for behavioral health services furnished by marriage and family therapists and mental health counselors.

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340B Program

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		President's Budget	+/- FY 2023 Enacted
340B Drug Pricing Program/Office of Pharmacy Affairs	12,238	17,238	+5,000

TALKING POINTS:

- The 340B Program is a critical drug discount program for safety net providers that serves **every congressional district** in the country.
 - Eligible entities include community health centers, Ryan White HIV/AIDS clinics, rural hospitals, and children's hospitals.
- I know that **program integrity** is critical and that is why the President's budget includes proposals to strengthen compliance, transparency and integrity of the program.
 - Right now, HHS does not have the authority to require reporting by covered entities on how they spend their savings. This budget requests new regulatory authority to require covered entities to annually report to HHS how the savings achieved through the Program benefits the communities they serve.
 - The Budget also proposes explicit regulatory authority to strengthen compliance and transparency related to the use of contract pharmacies.
- The Biden-Harris Administration is committed to **lowering the cost of drugs** and increasing access to affordable care. The 340B program is critical to this work and I look forward to working with Congress on these proposals to strengthen the program.

Questions:

Q: What is in the FY 2024 Budget for the 340B program? Why are you asking for more funding if the hospitals are exploiting the program?

- The FY 2024 Budget Request for the 340B Program is \$17.2 million, an increase of \$5 million over FY 2023, to strengthen the program's operations.
- The FY 2024 Budget includes a proposal to enhance 340B Program integrity by requiring covered entities to annually report to HHS on how the savings achieved through the Program benefits the communities they serve and provide HHS regulatory authority to implement this requirement.
- The Budget also proposes explicit regulatory authority to strengthen compliance and transparency related to the use of contract pharmacies.
- We look forward to working with Congress on these proposals to strengthen the 340B Program.

Program Information

BACKGROUND:

- The 340B Program requires drug manufacturers that participate in Medicaid to provide discounts on outpatient prescription drugs to certain safety net health care providers specified in statute, known as covered entities.
- Covered entities generate savings on their purchases of outpatient prescription drugs – typically by paying the discounted prices for drugs and billing insurers at standard rates and utilizing the difference.
 - These entities include Federally Qualified Health Centers, Children’s Hospitals, Critical Access Hospitals, Ryan White HIV/AIDS Program Grantees, and certain disproportionate share hospitals.
- Currently there are over 13,600 covered entities, as well as more than 800 drug manufacturers that participate.
- The 340B price is determined based on a statutory formula. The term “covered outpatient drug” is defined by CMS and these drugs must be used on an outpatient basis.
- The Biden-Harris Administration has taken a number of actions to protect and strengthen the program, including issuing Violation Letters to drug companies that restricted the use of outside pharmacies (“contract pharmacies”) to fill prescriptions for 340B drugs and proposing a new regulation for an Administrative Dispute Resolution process to replace the Trump Administration regulation and make the process more accessible and efficient.
- In the last three months, HRSA has issued a survey to 340B entities on how they are spending their savings and investing them in the community. We may not have the statutory authority to require reporting, but we are taking steps to improve transparency and accountability for 340B.

988 Implementation

TALKING POINTS:

- 988 is more than a number, it's a message: we're there for you. The transition to 988 is just the beginning. We are working towards comprehensive, responsive crisis care services nationwide to save lives.
- Investments in the 988 Lifeline through FY23 appropriations and the Bipartisan Safer Communities Act expanded lifesaving behavioral health services across the country.
- The FY24 budget requests an increase of over \$334 million to scale and strengthen the 988 crisis care enterprise for the 9 million contacts anticipated in FY2024.

QUESTIONS:

Q: How many contacts did the Lifeline answer last year? How quickly?

- From July 2022 to January 2023, the 988 Lifeline answered 2,248,545 million contacts.
- Thanks to historic investments made by Congress, calls answered increased by 57%, chats answered increased by 264%, and texts answered increased by 1608% between January 2022 and January 2023.
- The average speed to answer across all contacts decreased from 181 seconds to 40 seconds.

Q: Does the 988 Lifeline take calls in Spanish?

- Yes, in 2022, the 988 Lifeline increased the number of call centers taking Spanish calls -- this includes, most recently, Beacon in New Hampshire and Linea Pas in Puerto Rico, which were both added in November.
- SAMHSA is working to add Spanish chat and text services by October of this year and is focused on supporting the Spanish crisis center workforce with trainings and webinars in Spanish.

Q: I heard that there was a Lifeline outage in December 2022 as a result of a malicious attack. What steps is SAMHSA taking to ensure that the Lifeline is secure?

Our highest priorities are to develop additional redundancies in the event of any future outages, minimize the likelihood of these events, continue to protect personal information, and to be sure there are clear communications protocols among partners and the public to quickly resolve problems if they arise.

Q: What is the response rate right now for text, chat and calls?

- The total overall contacts has been above 400k each month and continues to trend up. Accordingly, we are projecting roughly 6 million contacts for FY2023 and the need to support 9 million contacts in FY2024.
- Since July 2022, we have maintained above a 95% response rate for chat and text.

- There was increase in the call response rate from Aug (i.e., 84%) to Jan (i.e., 88%). This is also notable as the contacts increase and we work to expand access and strengthen the network.

Q: Was any personal information obtained, as a result of this attack?

- Based on all available evidence that we have reviewed at this point, it is unlikely that any data were breached or exfiltrate

Program Information

Background:

- SAMHSA's National Suicide Prevention Lifeline transitioned to the 988 Suicide and Crisis Lifeline in July 2022. SAMHSA is working across HHS and the Dept. of Veterans Affairs to ensure the success of the Lifeline and to better integrate 988 with the crisis care continuum and community supports.
- Specifically, SAMHSA is working on expanding and improving 988 to ensure that it is responsive, culturally relevant, and meeting crisis care needs effectively and equitably.
- Thanks to historic investments made by Congress, in January 2023 vs. January 2022, calls answered increased by 57%, chats answered increased by 264%, and texts answered increased by 1608%.
- Data for January 2023 showed an increase in overall volume compared to January 2022, and showed that we answered 189,102 more contacts (calls, chats and texts) and significantly improved how quickly contacts were answered; the average speed to answer across all contacts decreased from 181 seconds to 40 seconds.
- Comprehensive crisis care systems include core services such as crisis contact centers, mobile crisis teams, and crisis receiving and stabilizing facilities. The current crisis infrastructure differs state by state and is highly dependent on available workforce.
- SAMHSA and HHS are working to bring different types of providers into the crisis response system in order to maximize the workforce we currently have, while ensuring that everyone has access to immediate care.

Abortion Riders

TALKING POINTS:

- I understand people have deeply held beliefs on this issue and I respect that.
- Reproductive health decisions should be between a patient and doctor.
- HHS will continue to enforce the law.

Questions:

Q: The budget excludes the Hyde amendment. Are you going to ignore the law?

- As you know, this is a provision included in funding bills passed by Congress, so it will be up to Congress on whether that changes.

Q: Do you support partial-birth abortion?

- I support access to reproductive care, including safe and legal abortion care.
- Reproductive health decisions should be between a patient and doctor.
- HHS will continue to follow the law.

Q: The Budget still leaves in place the Weldon Amendment and other abortion riders for other federal programs like IHS or FEHBP. Do you support this?

- The President has made clear that removing barriers to accessing reproductive care is a priority. The budget takes important steps to remove such barriers.
- Ultimately, removing the appropriations policy riders that restrict access to abortion is up to Congress and HHS will continue to enforce/follow the law.

ACA: Short Term Limited Duration Insurance (STLDI) Plans

TALKING POINTS:

- Making sure that all Americans have access to quality, affordable health care is one of the Biden-Harris Administration's top priorities.
- Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it.
- To make sure consumers are protected and understand the health insurance they are buying, the administration has stated its intention to revise the short-term limited duration insurance plan regulation.

QUESTIONS:

Q: Many Americans rely on Short-Term, Limited Duration Insurance plans because they are cheaper and don't come with all the unnecessary coverage mandated by the Affordable Care Act. Choice is so important in driving down the cost of insurance, so why are you committed to getting rid of this choice for consumers?

- Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. STLDI plans are exempt from critical Federal requirements for health insurance such as those contained in the Affordable Care Act. I am focused on expanding access to quality health insurance for all Americans, including ensuring consumers with pre-existing conditions are fully protected.

Q: Junk plans continue to trick consumers into buying their shoddy products. When will the Biden Administration take action to limit the availability of Short-Term, Limited Duration insurance plans?

- Thank you for your work on this issue. You're right. Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. To that end, this administration has stated our intention to propose amendments to the definition of 'short-term, limited-duration insurance' under the Public Health Service Act. At HHS, we are focused on making sure that all Americans have access to quality, affordable health care, and I would be happy to keep working with you on this issue.

Program Information

BACKGROUND:

Short-Term, Limited Duration Insurance Plans (STLDI)

The Trump administration extended the potential duration of STLDI plans from three months (set during the Obama regulation) to, effectively, three years. These plans often have lower premiums because they are not required to comply with ACA market reforms, such as the prohibition on pre-existing condition exclusions or guaranteed issue. These plans can be subject to state regulation, but state regulation varies by state.

ACA - Standardized Plans

TALKING POINTS:

- The Biden-Harris Administration has made it a priority to build on the success of the Affordable Care Act (ACA) by continuing to invest in and strengthen the law.
- Thanks to the American Rescue Plan (ARP) and Inflation Reduction Act (IRA), more people this year continued to qualify for help purchasing quality health coverage with expanded financial assistance, and a record-breaking more than 16.3 million people signed up for high-quality, affordable health insurance through the ACA Marketplaces during the 2023 Marketplace Open Enrollment Period.
- In accordance with President Biden's Executive Order on Promoting Competition in the American Economy, and based on new measures finalized in regulation, we have taken additional steps to further simplify the consumer shopping experience beginning in 2023 by requiring issuers offering Qualified Health Plans on HealthCare.gov to also offer standardized plan options.

QUESTIONS:

Q: There is no one-size-fits-all plan design that meets every enrollee's unique health needs. Won't standardized plans unnecessarily restrict consumers choices?

- Issuers are allowed to offer non-standardized plans.
- Standardized plans do not standardize covered benefits.
- Standardized plans help consumers better express their preferences with their plan selections.
- With standardized maximum out-of-pocket limitations, deductibles, and cost-sharing features, consumers are now able to more easily and meaningfully directly compare plans attributes they most care about, such as premiums, provider networks, prescription drug coverage, and quality ratings when choosing a plan, rather than trying to weigh the impacts of small variations in copays or co-insurance requirements that are unlikely to be known by the consumer.
- These standardized plan options also expand the availability of coverage for services before consumers meet their deductibles (including for prescription drugs at the generic and preferred brand tiers at most metal levels), which makes it easier to access important services.

Q: Why is HHS proposing to limit consumer choice in the 2024 Payment Notice? Why do you want to eliminate plan options?

- In the 2024 Payment Notice proposed rule, HHS proposed to limit the number of non-standard plans that marketplace issuers can offer up to two non-standardized plan options per product network type and metal level (excluding catastrophic plans), in any service area for 2024 and later years.

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- The average number of plans available to consumers on the Marketplace has increased from 25.9 in 2019 to 113.6 in 2023 – a more than fourfold increase in just four years.
- A large body of research indicates that having this excessive rate of plan proliferation increases the risk of plan choice overload, which limits consumers' ability to make a meaningful selection when comparing plan offerings and increases the risk of suboptimal plan selection – and thus unexpected financial harm for consumers who can least afford it.
- The marketplace is made up of very active consumers. For example, each year, approximately 75% of returning consumers come in to shop and actively select their plans.
- In the 2024 Payment Notice proposed rule, we sought comment on this and other issues related to simplifying plan choice, and we are currently reviewing these as we work to develop a final rule.

Alzheimer's Drug Coverage

Talking Points:

- We lived [through] this, my wife and her siblings and their families. We became caregivers.
- Alzheimer's disease is a devastating illness that affects millions of Americans and their families. HHS is committed to helping people get timely access to treatments and improving care for people with Alzheimer's disease and their families.
- When evaluating new treatments for Medicare coverage, CMS is required to examine whether a medication is *reasonable and necessary*.
- There has not been an Alzheimer's treatment approved by the FDA on the basis of clinical benefit.
- Under the current coverage pathway, people with Medicare can access newly FDA-approved Alzheimer's medications through clinical trials.
- This allows people with early-stage Alzheimer's disease to access these drugs through Medicare, while additional evidence on the treatments' effectiveness in real-world settings is gathered.
- CMS will expeditiously review any new evidence that becomes available that could lead to a reconsideration and change in the current coverage framework.

If pressed on FDA vs. CMS decisions:

- FDA and CMS have different legal authorities to use when considering product approvals, for FDA, and coverage, for CMS. The FDA makes approval decisions based on whether a product is safe and effective while CMS makes coverage decisions based on whether something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- These two processes are separate and run independently by the two agencies. Importantly, however – unlike traditional approval – FDA's accelerated approval pathway does not require finding that a new product demonstrates clinical benefit based on a clinical measure (e.g. how a patient feels or functions) but instead on the effect on a surrogate endpoint that FDA determined reasonably likely to predict clinical benefit; in other words, granting accelerated approval does not provide CMS with absolute certainty that there will be a clinical benefit.

QUESTIONS:

Q: Why did CMS deny the Alzheimer's Association's request for an NCD consideration?

- There has not been an Alzheimer's treatment approved by the FDA on the basis of clinical benefit.
- CMS issued a Federal Register notice regarding the necessary criteria for a reconsideration. As these criteria were not met as of the time of the request, CMS denied Alzheimer's Association's request for an NCD reconsideration.

- CMS will continue to monitor the evidence and engage in discussions with all interested parties.
- CMS is committed to reviewing evidence supporting an NCD reconsideration.

Q: What are the differences in coverage decisions by Medicare for Aduhelm and lecanemab?

- There are no differences in the coverage decisions for Aduhelm and lecanemab.
- Currently, both Aduhelm and lecanemab have received accelerated approval from the FDA.
- If FDA approves Aduhelm, lecanemab, or any other anti-amyloid mAb based on a validated measure of clinical benefit, broader coverage using the current framework under Coverage with Evidence Development, would be available on the same day.

Q: Doesn't CMS believe the FDA does a good job? Why is CMS rethinking what FDA already decided?

- The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies.
- The FDA determines whether to approve a new medical product based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use.
- CMS can conduct its own independent review to determine whether an item or service should be covered nationally by Medicare, including examining whether it is reasonable and necessary for use in the Medicare population.

Q: Why is CMS continuing to refuse to cover new Alzheimer's drugs that have been approved by FDA and are now being covered by other federal programs including the Department of Veterans Affairs?

- It is our understanding that the U.S. Department of Veterans Affairs has issued important exclusion and inclusion criteria for its own coverage of this drug using statutory authorities that are different from what Medicare uses. By statute, CMS is required to make coverage decisions based on whether something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- ***If pressed:*** Because of the early evidence and the immense burden of this devastating disease on the Medicare population, the Medicare National Coverage Determination (NCD) provides coverage with evidence development to support rigorous studies to help answer whether this drug improves health outcomes for patients, and includes a coverage pathway for broader access to these drugs if they receive FDA traditional approval.

Q: When will CMS reconsider this national coverage determination (NCD) to determine whether these treatments/drugs are reasonable and necessary? How long would it take to reconsider this NCD?

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- If new evidence emerges that addresses all outstanding questions, as outlined in the NCD, CMS will move swiftly to review and consider whether a reconsideration is warranted.
- ***IF PRESSED ABOUT THE NCD PROCESS:*** In the case of the Alzheimer's accelerated approvals, CMS determined a national coverage determination was needed because the current evidence shows that, while there may be the potential for clinical benefit, there is also the potential for serious harm to patients. (This harm may range from headaches, dizziness, and falls, to other potentially serious complications such as brain bleeds.)

Q: Why was the NCD process applied to this drug and not to other accelerated approvals for oncology drugs, which also have risks?

- CMS follows a long-standing process developed by Congress to determine whether a medical item or service (e.g., device, drug, preventive service) is reasonable and necessary for the diagnosis of and/or treatment of an illness or injury in the Medicare population.

Q: Have you used the NCD process before for other drugs?

The NCD process is defined in statute (section 1862(l) of the Social Security Act) and is generally how Medicare considers requests for coverage of new items and services. One recent example of CMS's use of the NCD process is for coverage of CAR T-cell therapies.

Q: Has CMS used the coverage with evidence development determination for other drugs or devices?

Yes, CMS has finalized over 20 coverage with evidence development (CED) NCDs.

Program Information

BACKGROUND:

- In April 2022, CMS laid out how Medicare covers FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer’s disease. In the NCD, CMS stated it was interested in data that could answer the following questions:
 - *Does the anti-amyloid mAb meaningfully improve health outcomes (i.e., slow the decline of cognition and function) for patients in broad community practice?*
 - *Do benefits and harms, such as brain hemorrhage and edema, associated with use of the anti-amyloid mAb, depend on characteristics of patients, treating clinicians, and settings?*
 - *How do the benefits and harms change over time?*
- CMS follows a formal, standardized process to develop or reconsider NCDs that includes opportunities for the public to participate and submit comments. Per the statute, CMS generally issues a proposed NCD and accompanying decision memorandum within six months of the initiation of the NCD analysis. When the proposed NCD is issued, it will initiate a 30-day public comment period with the final NCD due within 60 days from end of the 30-day public comment period.

⁽¹⁾ <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf>

ARPA-H

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
ARPA-H	1500	2500	+1000
Total Program Level	1500	2500	+1000

TALKING POINTS:

- The FY 2024 request for ARPA-H includes \$2.5 billion, an increase of +\$1 billion, to build on the success of the agency and continue progress towards achieving the President’s vision.
 - The requested funding will support the recruitment of additional Program Managers and will support projects in key technical focus areas to drive transformational innovation in health and speed the application and implementation of health breakthroughs.
- We are thankful to Congress for permanently authorizing ARPA-H and for the work that Dr. Wegrzyn has done since arriving in October. One of the authorities bestowed on the agency by Congress allows them to actively recruit the best minds to tackle the hardest problems in health. ARPA-H will continue to aggressively recruit talented program managers and build a portfolio of programs across the health innovation landscape.
- ARPA-H now has its first technical team leaders in place, and they anticipate hiring approximately 15 Program Managers by the end of the year. Looking into FY 2024, the agency anticipates doubling the number of Program Managers and programs.

QUESTIONS:

Q: Where will ARPA-H be located?

- ARPA-H recently announced their intention to establish sites in three different geographic locations, in accordance with legislation.
- In order to fulfill the agency’s mission and the President’s vision, ARPA-H must seek the best ideas from all over the country, and serve all Americans, wherever they may be.
- Unfortunately, access to healthcare and innovation can be challenging for Americans, depending on the geography where they are located.
- ARPA-H embraces the opportunity to expand beyond a single location, and intends to use the three sites to accelerate transformational breakthroughs in health by directly connecting ARPA-H with stakeholders, customers, investors, and transition partners.

- The first site will focus on stakeholders and operations and will be established in the Washington, DC area. This will put ARPA-H near key stakeholders, Congress, HHS, CMS, FDA, NIH, the White House, and other federal partners that are essential to their mission.
- Having a location near the majority of our nation's regulatory and legislative partners is crucial.
- In addition to this location, ARPA-H will also be seeking proposals to identify two sites in different regions of the U.S.
- The remaining two sites will serve as hubs, forming the foundation of a hub-and-spoke health innovation network, which will feature numerous spokes across the United States.
- Selection for these remaining two sites will be through an open and competitive process open to any geography in the U.S.
- ARPA-H will not compete the location of the Stakeholder and Operations hub site, but will rely on standard GSA and leasing processes to identify a suitable site.
- ARPA-H will have a nationwide network and part of that network will be in D.C. it is only one of their sites, they will have 3 hubs total each with important roles to fill for the agency.
- No matter where the agency is physically located, its funding will support the best and brightest ideas across the country.

Q: ARPA-H has received \$2.5 billion over the last two fiscal years, we are concerned they will not be able to obligate such an increase, are you confident they will be able to?

- The Department and the Administration fully supports achieving the President's vision for ARPA-H and realizing transformational change and accelerating health outcomes for everyone. Since Dr. Wegrzyn was sworn in as the inaugural director in October, the agency has made tremendous progress. Congress permanently authorized the agency and provided a +50% increase in appropriated funding for its second year in existence. During the first quarter 2023, ARPA-H hired their first program managers and expect programs to begin shortly. The agency has already; established operations across all functional areas, hired more than 100 professionals with extensive experience across the health, science, and technology landscape, and met with hundreds of stakeholders from patient advocates to providers to investors. The agency has done all this in just a few months and is in a place where they are ready to hit the ground running to achieve their mission.

Q: How will ARPA-H stay independent from NIH?

- ARPA-H and NIH are complements with one another and both are members of the health innovation ecosystem. ARPA-H and NIH funding is invested in different types of innovation. ARPA-H looks to address health problems that cannot be readily accomplished through traditional research or commercial activity. Both agencies have the goal of improving the health of everyone but will achieve that with different methods.

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- It is also important to note that ARPA-H is a stand-alone entity and is not a NIH Institute or Center, and will not be located on the NIH Campus. While the Consolidated Appropriations Act of 2023 places ARPA-H within the NIH, the ARPA-H Director reports directly to me and the ARPA-H budget is also separate from NIH.

Behavioral Health

(Dollars in Millions) Discretionary Funding

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	5	5	--
HRSA	2,034	2,500	+466
IHS	394	473	+79
CDC	1,090	1,754	+663
NIH ²	8,199	8,382	+183
SAMHSA	7,518	10,422	+2,904
AHRQ	8	20	+12
CMS (discretionary)	5	8	+3
Total Discretionary Program Level	19,253	23,565	+4,312

¹ The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year.

² The FY 2023 Enacted and FY 2024 amounts are estimates and subject to change as NIH finalizes internal allocations.

TALKING POINTS:

- This budget invests \$4 billion more in discretionary funding in meeting behavioral health needs, including funds to increase access to crisis services and grow the behavioral health workforce.
- Suicide is the second leading cause of death for people between ages 10 and 34. The budget includes \$836 million to the 988 and Behavioral Health Crisis program, an increase of +\$334 million, to ensure capacity for the Lifeline to provide life-saving **crisis services** to the estimated 9 million 988 contacts in 2024.
- The budget invests in the **behavioral health workforce** by supporting an estimated 27,000 total mental health and substance use disorder trainees and providers. Specifically, the budget proposes \$387 million for Behavioral Health Workforce Development Programs, an increase of +\$190 million, to grow the number of behavioral health professionals through training approximately 18,000 behavioral health providers; such as psychiatrists, psychologists, clinical social workers, marriage and family therapists, counselors, and peer support specialists.
- The +\$168 million increase to the Certified Community Behavioral Health Centers program will serve 89,000 more people, providing life-saving, 24/7 care to 400,000 Americans. These services benefit them in real ways such as a documented 74% reduction in mental health hospitalizations and a 31% increase of functioning in everyday life.

- Certified Community Behavioral Health Clinics provide high quality, cost-effective **behavioral health services** when and where patients need them. With \$20.1 billion in Medicaid matching funds over 10 years, the budget converts the existing demonstration into a permanent option.
- Currently, the Certified Community Behavioral Health Centers demonstrations are time-limited, with enhanced federal match ending after the demonstration period. We've seen that states who set up these demonstrations serve more patients and see positive results over time. In the first 8 states to participate in the demonstration, Certified Community Behavioral Health Centers served nearly 54,000 more people in their second demonstration year compared to their first. By making Certified Community Behavioral Health Clinics a permanent program, states can use the program in a sustainable way that works for them.
- The budget improves access to behavioral healthcare in Medicare and the private insurance market by requiring coverage of three behavioral health visits and three physical care visits without cost-sharing.

QUESTIONS:

Q: How does the budget address the youth mental health crisis in the United States?

- We have seen a significant increase in mental health needs among youth, including depression, anxiety, and suicidal ideation. The budget includes investments in several programs addressing youth mental health, including Project AWARE, the National Child Traumatic Stress Network, and the Children's Mental Health Services program.
- The nation's mental health crisis is also disproportionately impacting our most vulnerable youth. In 2021, lesbian, gay, and bisexual youth reported greater levels of poor mental health. The budget request for the 988 Lifeline will support specialized services for LGBTQI+ youth to ensure tailored services for this important population.

Q: Some populations are at higher risk of behavioral health concerns—how does the budget focus investments on communities that need it most?

- Suicide risk is disproportionately high for tribal populations, sexual and gender minorities, middle-aged adults, and veterans. The budget proposes a significant increase for the 988 Lifeline, which includes supports for LGBTQI+ youth and services for Spanish speakers. The budget also includes an increase within the Indian Health Service to provide services to American Indian and Alaska Native patients, including suicide prevention, treatment for substance use disorder, and both in person and tele-behavioral health services.
- Individuals with a mental illness are also more likely to experience homelessness than those without mental illness, and they experience homelessness longer than the rest of the homeless population. The budget proposes to provide \$110 million for SAMHSA's Projects for Assistance in Transition from Homelessness program, an increase of +\$43 million above FY 2023 enacted, to expand the number of communities served and

substantially increase the number of participating providers, resulting in 212,000 individuals contacted and 119,000 individuals enrolled in FY 2024.

Q: To improve access to care, the nation needs more behavioral health providers. How does the budget address this need?

- HHS is committed to advancing the recruitment, training, and supporting a diverse behavioral health workforce. The budget includes \$37 million for SAMHSA's Minority Fellowship Programs, an increase of \$17 million over FY 2023 enacted, to almost double the number of fellows. The budget proposal includes a new service requirement to ensure Fellowship participants are supporting communities in need. The budget also proposes historic investments in HRSA to support further expansion of the behavioral health workforce.

Q: How does the budget improve mental health parity?

- Medicare beneficiaries with mental health and substance use disorders are just as deserving of protection and care as those with medical, physical, or surgical needs. Unlike most private and employer-based insurance and Medicaid plans, Medicare is not subject to the 2008 Mental Health Parity and Addiction Equity Act, which requires health plans that offer mental health and substance use disorder benefits to provide coverage on par with the medical and surgical benefits they offer. Applying parity to Medicare will ensure that Medicare behavioral health benefits do not face greater limitations relative to medical and surgical benefits. The budget invests \$1.2 billion in HHS funding to strengthens mental health parity on the private insurance market by requiring all plans to cover mental health and substance use disorder services, eliminating loopholes that have resulted in disparate coverage practices, and requiring plans to cover three behavioral care visits with no beneficiary cost sharing.

Q: How much will Americans save in copayments from requiring three behavioral health visits without cost-sharing?

- The amount of money that individuals will save depends on the benefit and cost-sharing structure of the plan that the individual is enrolled in. For example, an individual enrolled in a silver-level Marketplace plan with an applicable co-payment for behavioral health services will save an average of \$34 per visit (\$102 for first three visits). An individual enrolled in a plan where the deductible must be met before cost-sharing limits apply may save an average of \$100-200 per visit (\$300-600 for first three visits).
- Coinsurance for a typical Medicare behavioral health visit would be \$15 to \$20.

Q: How does the budget improve behavioral health integration?

- Behavioral investments throughout the budget support integration efforts. Just to name a few specific proposals:

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- \$103 million, an increase of \$47 million, for SAMHSA’s Primary and Behavioral Health Care Integration program, to advance the integration of physical and behavioral health care using evidence-based models of care.
- \$90 million, an increase of \$52 million, to allow to CDC scale up the *What Works in Schools* program from 28 up to 75 local education agencies nationwide. This program strengthens the integrated delivery of mental health promotion and treatment interventions to students and families across a range of care settings.
- \$5 million in funding for AHRQ to research and understand how to scale existing Local Integrated Care Network models – which provide behavioral health support systems for primary care practices.

Program Information

The budget increases discretionary investments to address mental and behavioral health in the United States with increases across HHS totaling \$23.6 billion including:

- **FDA:** A total of \$5 million to support the review and approval of products to increase access to treatments to improve health outcomes for those affected by behavioral and mental health conditions, including drug abuse. Activities include research of drugs with abuse potential and abuse-deterrent efforts; review of clinical outcomes to assess behaviors; participation in social and behavioral science research studies; and education, communication, and stakeholder outreach. FDA also conducts behavioral health research such as work with traumatic brain injury and early detection of stroke, neuro-degeneration, and other Central Nervous System conditions.
- **HRSA:** +\$466 million above FY 2023, for a total of \$2.5 billion to support advancing equitable access to behavioral health services with historic investments in the behavioral health workforce development, including psychiatry, crisis care, peer support, nursing, primary care, and substance use disorder practitioners, and integrating these services into primary care settings. This investment also funds an innovative approach to recruiting, supporting, and training new providers to address significant concerns about workforce shortages. The budget also includes a new pilot program in HRSA to enable Rural Health Clinics to establish new and expanded behavioral health in rural communities.
- **CDC:** +\$664 million above FY 2023, for a total of \$1.8 billion to support a variety of mental and behavioral health investments such as: drug overdose prevention and surveillance, community violence intervention, suicide prevention, adverse childhood experiences, gun violence research, school health, tobacco prevention and control, viral hepatitis prevention, and domestic HIV/AIDS prevention and research.
- **IHS:** +\$79 million above FY 2023, for a total of \$473 million to support funding for the IHS Mental Health and Alcohol and Substance Abuse programs. These programs provide a broad range of services to American Indian and Alaska Native patients including suicide prevention, treatment for substance use disorder, and both in person and tele-behavioral health services. In FY 2024, general funding increases will support an estimated 955,662 outpatient mental health services and 88,701 outpatient and inpatient substance use treatment days.
- **NIH:** +\$183 million above FY 2023, for a total of \$8.4 billion for behavioral and social sciences research including aspects of mental health and substance use disorders that are related to behavioral health.
- **SAMHSA:** +\$2.9 billion above FY 2023, for a total of \$10.4 billion in discretionary funding to provide an historic investment in Behavioral Health Crisis Services; expand access to crisis services; ensure access to early intervention and prevention services to the nation's vulnerable populations; invest in children's mental health; respond to the ongoing opioid and substance use crisis, ensure access to naloxone and overdose prevention services, and invest in prevention and recovery support services.

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- AHRQ: +\$12 million above FY 2023 Enacted, for a total of \$20 million to support the Secretary's initiative to combat opioid misuse and overdose through opioid research and research exploring the need to increase access, quality, and equity of behavioral health services, including management of mental health and substance use in primary care, and improve the integration of behavioral health and primary care.
- CMS: +\$3.0 million above FY 2023, for a total of \$8.0 million in discretionary funding to support continued CMS efforts to implement and to sustain provisions of the SUPPORT Act that address improved behavioral health; access to SUD prevention, treatment and recovery services; and data for effective actions and impact. As part of ongoing SUD support efforts, CMS will continue to develop IT infrastructure to process electronic prescribing of controlled substances (EPCS) waivers and enforce compliance for Medicare Part D prescriptions.
- **The budget increases mandatory investments to address mental and behavioral health in the United States:**
 - OASH: A mandatory proposal investing \$2 billion over ten years to respond to the President's call for full parity between physical health and mental health care by creating a new Mental Health System Transformation Fund. This fund will be used to expand access to mental health services through mental health workforce development and service expansion, including the development of non-traditional mental health delivery sites and dissemination of evidence-based practices, and extension of quality mental healthcare delivered in less traditional settings such as community health centers.
 - SAMHSA: A mandatory proposal investing \$412 million per year over 10 years to direct funding to Community Mental Health Centers. This program will increase access to high quality mental health services in communities across the United States.
 - HRSA: A new mandatory proposal investing \$700 million in resources to more than double the current Health Center Program behavioral health services investments including a legislative proposal to require all health centers provide mental health and substance use disorder services. The budget proposes to extend mandatory funding for National Health Service Corps over three years with \$790 million in FY 2024, for a total investment of \$2.4 billion through FY 2026. NHSC funding supports scholarships and loan repayment to primary care, dental, and behavioral health providers in return for their service in underserved urban and rural areas. The budget also includes \$157 million in mandatory resources for residency training in primary care medicine and dentistry in community-based, ambulatory settings and extends funding through FY 2026 for a total investment of \$841 over three years.
 - CMS:
 - Medicare: The budget invests over \$3.9 billion over 10 years for Medicare proposals to improve Medicare coverage and make access to care more affordable. This includes proposals to eliminate the 190-day lifetime limit on psychiatric hospital services and require Medicare to cover three behavioral health visits per year without cost-sharing. In addition, the budget supports other proposals to modernize Medicare

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fee-for-service mental health benefits, revise the criteria for psychiatric hospital terminations from Medicare, and apply the Mental Health Parity and Addiction Equity Act to Medicare.

- Medicaid: The budget makes permanent the CCBHC program, ensuring Medicaid provides a sustainable source of reimbursement for these clinics, and expands mental health capacity for State Medicaid programs.
- Private Insurance: The budget improves access to behavioral healthcare in the private insurance market by requiring all plans and issuers, including group health plans, to provide mental health and substance use disorder benefits while also requiring coverage of three behavioral health visits and three physical care visits without cost-sharing. The budget total \$46.9 billion, including \$1.2 billion in HHS.

BACKGROUND:

Overdose Epidemic:

- The budget addresses the **overdose epidemic** by investing \$10.9 billion, including \$9.8 billion in discretionary funding, in programs addressing opioids and overdose-related activities across HHS. These programs support the goals of the HHS Overdose Prevention Strategy.

Bipartisan Safer Communities Act (BSCA)

TALKING POINTS:

- The Bipartisan Safer Communities Act (BSCA) which was signed into law by President Biden last summer strengthens the mental health care system, school safety programs, and gun safety laws – further advancing the President’s whole-of-government mental health strategy, which he launched as part of his Unity Agenda.
- HHS has worked hard to get funding in the bill out the door as quickly as possible.
 - See Grant Award funding below.

If asked about grant funding:

- BSCA provided \$800 million in funding to SAMHSA for behavioral health grants, including:
 - \$250 million for Community Mental Health Services Block Grants,
 - \$240 million for Project Advancing Wellness and Resiliency in Education (Project AWARE),
 - \$120 million for Mental Health Awareness Training,
 - \$40 million for the National Child Traumatic Stress Network
 - \$150 million for the new 988 Suicide & Crisis Lifeline.
- All BSCA funding for the 988 Lifeline has been obligated.
- HRSA announced \$60 million in Primary Care Training and Enhancement awards and \$15 million in Pediatric Mental Health Care Access awards, with more to come.

If asked future opportunities:

- The law includes a nationwide expansion of Certified Community Behavioral Health Clinics (CCBHCS).
 - We recently awarded planning grants to 15 states.
 - After one year of state planning, they are expected to apply to participate in the demonstration program funded through Medicaid, and 10 states will be selected to start as soon as July 2024.
 - Ultimately, every state will have the opportunity to participate.
- CMS is working to:
 - Award \$50 million in grants towards implementing, enhancing, or expanding the provision of assistance through school-based entities under Medicaid or CHIP.
 - Provide guidance and technical assistance on Medicaid telehealth services.
 - Review State Implementation of Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services.

Cancer Moonshot

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	2	50	+48
HRSA	11	21	+10
IHS ²	--	108	+108
CDC	656	839	+183
NIH ³	216	716	+500
Total Program Level	885	1,733	+849

1/ The FY 2023 President's Budget proposed a one-time increase of \$20 million for FDA's cancer moonshot activities. The funds were requested with three-year availability. The House mark provided \$7M as an annual base increase and not as a one-time increase.

2/ The FY 2023 Budget and all FY 2024 columns propose IHS funding as mandatory.

3/ Funding level reflects authorized CURES and non-CURES funding

TALKING POINTS:

- The reignited Cancer Moonshot includes the specific aim of **cutting the cancer mortality rate in half within 25 years.**
- We will build upon the successes of the foundational Moonshot programs (e.g., improving immunotherapy for adult and pediatric cancers, exploring drug resistance, boosting efforts for collecting/sharing cancer data) to continue to improve prevention, diagnosis and treatment outcomes and quality of life for all people.
- In February we hit the one-year anniversary of President Biden's Cancer Moonshot Initiative. Key efforts to date include:
 - **Increasing Cancer Screenings in Underserved Communities:** In February HRSA awarded nearly **\$11 million to 22 health centers** to improve access to life-saving cancer screenings and early detection services for underserved communities. These awards double support for an initiative launched last year by the Biden-Harris Administration through which HRSA-funded health centers are working to close the cancer screening gap and decrease the impact of preventable cancers.
 - **Expanding NCI Clinical Trials:** This will allow the development of new and improved treatment options for people with cancer through novel clinical trials; We will also ensure that cancer clinical trials are available in the communities in which people live and receive their care.
 - **Establishing comprehensive infrastructure to share and process cancer data** and enabling the fullest possible use of all forms of research data while protecting patient privacy.

QUESTIONS:

Q: What is different about investments this time?

- The Obama-Biden administration delivered significant investments in cancer research activities that accelerated progress of prevention, diagnosis, and treatment programs.
- Because of this foundation, this Administration is now able to set the goal of reducing the death rate from cancer by at least 50 percent over the next 25 years.
- The President has now emphasized the need to focus on patients and their families living with cancer, a focus of HHS investments. We will continue to make foundational investments in cancer research, prevention, and care.
- We are investing in outreach and education efforts with \$20 million to support HRSA-funded health centers in reaching underserved communities and part of FDA's \$50 million Cancer Moonshot funds dedicated to research and education.

Q: What is NIH doing to diversify Clinical Trials?

- NIH remains dedicated to ensuring inclusion throughout its supported clinical research activities.
- NIH has longstanding policies to ensure appropriate inclusion of women and minorities, and individuals across the lifespan in clinical research.
- NIH has made several strides to ensure that clinical trials reach as many communities as possible and that we are held accountable for continuing these efforts. For example,
 - 29% of U.S. participants in NIH-funded clinical research identified as members of a racial or ethnic minority group (FY22 74% identified as white, 1.3% unknown, unreported).
 - Female participants represented 52%.
 - Children under 18 years represented 14% and adults older than 65 represented 21%.
- To facilitate greater diversity in clinical trials, it is crucial to establish and facilitate trust between the research community and local community members and leaders.
 - Lessons learned from the Community Engagement Alliance (CEAL) program which helped engage communities around COVID-19 are being applied to broader research contexts.

Q: What are you doing to address multi-cancer early detection?

- One year ago, President Biden reignited the Cancer Moonshot and set new national goals to cut the death rate from cancer by at least 50% over the next 25 years and improve the experience of people and their families living with and surviving cancer.
- At HHS, we are doing all we can to make cancer prevention and screening services accessible to everyone in the United States, including taking action to address the estimated 9.5 million cancer screenings missed during the pandemic.

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- I look forward to hearing more from you about increasing access to preventive health services, particularly for cancer prevention.
- HHS always appreciates the opportunity to provide technical assistance to Congress on important health care issues.

CCBHCs
(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Certified Community Behavioral Health Clinics (SAMHSA)	\$385	\$553	+\$168
Total Program Level (Discretionary Only)	\$385	\$553	+\$168

TALKING POINTS:

- The Certified Community Behavioral Health Clinic (CCBHC) model is designed to ensure access to coordinated and comprehensive behavioral health care. CCBHCs are required to serve anyone who requests care for mental health or substance use, regardless of their ability to pay, place of residence, or age - including developmentally appropriate care for children and youth.
- The Bipartisan Safer Communities Act provided funding to give every state the opportunity to participate in CCBHC demonstration program already successfully running in nine states. Fifteen states were recently awarded planning grant funding from the law, with more to come.
- The FY 2024 Budget converts the CCBHC demonstration to a permanent program and proposes a +\$168 million increase for SAMHSA’s CCBHC program.
- This investment into CCBHCs underscores the Biden-Harris Administration’s commitment to strengthening the mental health of all Americans, including people living in our nation’s most vulnerable communities. Behavioral health is health. Period. There should be no distinction. This investment will bring us closer to that reality.

QUESTIONS:

Q. How are state planning grants different from the CCBHC expansion grant program?

- State planning grants will help states prepare to participate in the CCBHC program funded through Medicaid. SAMHSA’s CCBHC Expansion grants are awarded directly to provider organizations.
- The purpose of the provider-level CCBHC Expansion grant is to support clinics to meet the CCBHC certification criteria and mainly support service development and delivery.

Q. How do the state planning grants work?

States that have completed planning grants will be eligible to apply to participate in the CCBHC Demonstration at the end of the year-long planning grant period.

Q. Can states that received planning grants in FY 2016 apply again in this round?

States that received planning grants in FY 2016, but were not selected to participate in the Medicaid Demonstration, can re-apply.

Q. How will states be selected for planning grants?

States' grant applications will be peer-reviewed, scored, and selected based on: statement of need, population of focus, proposed approach, staff and organizational experience, and data collection and performance measurement.

Q. What happens after the planning grant project period ends?

At the end of the planning grant period, participating states must submit their applications to join the CCBHC Demonstration for a four-year period starting on July 1, 2024.

CDC Moving Forward

TALKING POINTS:

- CDC Director Dr. Rochelle Walensky launched Moving Forward to strengthen CDC by strategically building on lessons learned during the COVID-19 pandemic to break down silos, reduce bureaucracy, and improve accountability.
- This effort will be critical to deliver health information more clearly and quickly to policy makers and American. We're already seeing the benefits of this effort:
 - CDC was the first in the world to produce data showing real-world effectiveness of the JYNNEOS vaccine for mpox.
 - Two public-facing databases went live in April 2022 that provide public health practitioners and the public with critical data about non-fatal overdoses and overdose deaths to tailor interventions in their communities.
- As CDC makes the changes it can internally, we also need help from Congress through funding and new authority to fully deliver on its mission of protecting the health, safety, and security of Americans.

QUESTIONS:

Q: Should Congress Authorize CDC and put in statute a clear organization structure?

- I want to be clear that CDC activities are authorized in the Public Health Service Act.
- Through Moving Forward, CDC has focused on lessons learned and is making important changes to break down silos, reduce bureaucracy, and improve accountability.
- As CDC makes the changes it can internally, we have also identified key policy changes that can only be achieved through Congress.
- My hope is that we can focus on these key areas to find bipartisan solutions to support the health, safety, and security of Americans.

Q: How will the reorganization allow CDC to better serve the American people?

- Reduce bureaucracy and improve accountability.
 - CDC elevated the offices of science, laboratory, and data to be in the Office of the Director.
 - These are cross-cutting offices that provide foundational support and should have direct access to the Office of the Director.
 - CDC combined two centers that supported relationships with jurisdictions, as well as workforce and infrastructure technical assistance.
 - This new center will provide clarity on where STLT should go for technical assistance and strengthen our working relationships with jurisdictions.
 - CDC elevated the Center for Preparedness and Response to the Office of the Director.
 - Response activities cut across CDC and are not siloed to one center.

Q: What changes has CDC already made?

- Share science and data faster
 - Improved timeliness of getting science out by reducing internal review times by 50 percent.
 - We were the first country in the world to produce data showing real world effectiveness of JYNNEOS.
- Translate science into practical policy
 - CDC's Overdose Data to Action (OD2A) databases
 - These two, public-facing dashboards include near real-time syndromic data on nonfatal overdoses in emergency departments as well as information on the circumstances and context of overdose deaths. The dashboards allow public health practitioners and members of the public with critical data to tailor interventions in their communities.
- Develop a CDC workforce ready to respond to future threats
 - Established CDC Ready Responder Program.
 - This program, deployed in December, is identifying, training, and assigning staff to response roles, to better serve partner organizations, and protect communities that are most at risk during emergencies.

Q: What does CDC need from Congress?

- A modernized data authority to receive and share back data more quickly. This allows CDC to forecast, track, and prevent the spread of emerging issues.
- Workforce authorities – numerous workforce authorities to build and support CDC's workforce to quickly respond and to sustain that response through a public health emergency.
 - Direct Hire
 - Overtime and danger pay
 - Tax waiver for loan repayment
 - Non-competitive conversion for term hires
 - Ready Response – budget flexibility to have a cadre of responders ready to go at a moment's notice.
- Vaccines for Adults
 - We must leverage what we built for COVID to create a sustainable adult vaccine infrastructure to be better prepared for the next pandemic and to improve vaccine access and equity across our population.

Countermeasures Injury Compensation Program (CICP)/Vaccine Injury Compensation Program (VICP)

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		President's Budget	+/- FY 2023 Enacted
Countermeasures Injury Compensation Program	7,000	15,000	+8,000
Vaccine Injury Compensation:			
Vaccine Injury Compensation Trust Fund (HRSA Claims)	256,370	261,497	+5,127
VICTF Direct Operations - HRSA	15,200	26,200	+11,000
Subtotal, Vaccine Injury Compensation	271,570	287,697	+16,127

TALKING POINTS:

- First, COVID-19 vaccines are the most safe and effective way to prevent yourself from severe harm and death from COVID-19.
- Second, HHS is actively working to process claims as **quickly** as possible, in compliance with the relatively **high standard** set out in statute that must be met for compensation.
- While the Agency has worked hard to hire additional medical reviewers and is implementing key process improvements, the additional resources in the Budget will help support the work to **address the backlog**.
- The President's Budget request is a step in the right direction.

QUESTIONS:

Q: If we meet your budget request this year, will it resolve the current CICP backlog, and how quickly? What else is needed?

- Last year's Budget proposed \$15 million to review additional CICP claims and compensate eligible individuals. However, only \$7 million was appropriated which supported the hiring of additional staff.
- The additional funds we are requesting this year would help expedite the processing of claims by hiring additional medical reviewers, streamline the review process to be more claimant friendly, and compensate claims.

Q: What is the impact of the end of the COVID-19 Public Health Emergency on COVID-19 claims in the CICP?

- The PREP Act Declaration for Medical Countermeasures against COVID-19 currently extends through October 1, 2024.

Program Information

BACKGROUND:

- The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to conduct an administrative review to determine whether, based on “compelling, reliable, valid, medical, and scientific evidence,” individuals who allege injury or death due to administration of a covered countermeasure are eligible for compensation.
- The PREP Act Declaration for Medical Countermeasures against COVID-19 currently extends through October 1, 2024.
- Prior to COVID-19, CICP had only received 500 claims.
- Since 2020, HHS has received more than 11,000 COVID-19 claims, including 8,447 claims alleging injuries from COVID-19 vaccines.

Potential for VICP Coverage of COVID-19 Countermeasures:

- Several members of Congress have also expressed interest in expanding the VICP to cover COVID-19 countermeasures.
- As of February 27, 2023, the VICP has a backlog of 1,433 petitions.
- For a category of vaccines to be covered by the VICP, the category of vaccines must be subject to an excise tax which requires congressional action and that has not happened.
- Before a transition would occur, there are several policy considerations that would need to occur to ensure that there is a smooth transition and that claimants are clear on the program they should submit their claim to.
- A transition would also require HHS, Department of Justice (DOJ) and the Courts to have the necessary resources to process the influx of claims the VICP program would gain.
- Once HHS determines the statutory requirements are met for a vaccine to be covered under the VICP, the HHS Secretary must first publish a notice of coverage in the Federal Register. In the past, this notice of coverage has usually been published shortly after the excise tax has been imposed on a category of vaccines.

Climate Health and Environmental Justice

TALKING POINTS:

- HHS is committed to addressing the impact of climate change on Americans' health and promoting climate resilience in the health care sector.
- As extreme heat events and hurricanes become more intense due to climate change, we need to understand and mitigate these impacts so our health systems are prepared.
- We also must make sure we are targeting our resources equitably to ensure that benefits accrue to communities that have been marginalized or overburdened by climate and environmental health hazards.

QUESTIONS:

Q: Why does HHS need an Office working on climate change? Doesn't EPA have health in their mission?

- Climate change is affecting our health today and putting lives at risk.
- Extreme heat events are predicted to happen more often and last longer due to our changing climate.
 - FACTOID: This past summer in Maricopa County, Arizona, [378 people died from heat](#). That number was up from the previous summer when [338 people died from heat](#).
- Hurricanes are becoming more intense due to climate change.
 - FACTOID: Hurricane Ian led to [at least 144 deaths](#) in Florida when it hit in September 2022, making it one of the worst hurricanes in state history. Two-thirds of the 144 confirmed deaths were people aged 65 years and older.
- While EPA has a role in protecting the environment and promoting public health, HHS is responsible for ensuring the resilience of our nation's healthcare systems.

Q: Is creating a new Office focused on climate change going to further strain our already overwhelmed healthcare systems?

- The recent heat dome event in Oregon and Washington and Hurricanes Ida, Ian, and Michael in Florida have shown us that the increasingly frequent and severe weather events caused by climate change are already causing hospitals to close and leading to illness and death.
 - FACTOID: Hurricane Ida [forced three damaged hospitals in Southeast Louisiana to evacuate 160+ patients](#). A massive failure of the electric grid forced hospitals to operate on generator power and rely on water from on-site wells.
- Failing to acknowledge and address this reality will only cause more harm to our most vulnerable citizens.
- The Office of Climate Change and Health Equity is already providing technical assistance and connections to existing federal resources to help health systems manage their growing risks associated with climate change.

Q: Congress hasn't given HHS any authority to regulate greenhouse emissions...why are you forcing Hospitals to reduce their emissions?

- The US health sector is responsible for roughly 8.5% of the nation's total greenhouse gas emissions. We are excited that over 830 hospitals have signed the White House/HHS Health Sector Climate Pledge to: cut their greenhouse gas emissions by 50% by 2030 and achieve net-zero emissions by 2050.
- With that said, the pledges made are voluntary; the organizations that signed this pledge are not obligated to report data on their progress to the federal government in association with this pledge.
- As I said from the moment we launched the Office, nothing is off the table when it comes to the policy levers the Department will deploy going forward. We will consider everything at our disposal and that could include regulatory action in the future.

Q: Why does HHS need its own Office of Environmental Justice? Aren't these issues covered under EPA and other departments?

- Protecting our nation's health from environmental harms requires working in partnership across government.
- Studies demonstrate that people of color and disadvantaged, vulnerable, low-income, marginalized, and indigenous populations are disproportionately burdened by environmental hazards.
- These populations are often exposed to unhealthy land uses, poor air and water quality, dilapidated housing, lead exposure, and other environmental health threats that drive health disparities.
- HHS has a key role in providing public health leadership and focusing human services to help meet the needs of these communities.
- One more point for a tangible example:
 - We're using the new Environmental Justice Index, developed by CDC/ATSDR, to show the cumulative burden of social, environmental, and underlying health factors in neighborhoods that would bear the brunt of transportation projects. For example, a tolling program in Manhattan that could increase air pollution in the Bronx should maximize health protections for already vulnerable communities.

Q: Our understanding is that both the Office of Climate Change and Health Equity and its Environmental Justice division have already been established. Congress did not appropriate funding for this Office in FYs 21, 22, or 23. From what resources has HHS funded the operations of this Office?

- I have determined that based on the importance of this work, my Secretarial Initiatives and Innovations funding would be used to support this work while we await dedicated Congressional funding.

Program Information

BACKGROUND:

Office of Environmental Justice

- The Office of Environmental Justice is leading initiatives that integrate environmental justice into HHS's mission.
- Since its creation in May 2022, this office has leveraged expertise across HHS to focus on disadvantaged communities and vulnerable populations across the nation.
- This office also provides leadership in HHS's implementation of the Justice40 initiative, which guides certain federal investments to flow into disadvantaged communities that are marginalized, underserved, and overburdened by pollution.
- **FACTOID:** Pollution is the largest environmental cause of disease and premature death in the world. It's responsible for nearly 9 million deaths per year, corresponding to one in six deaths worldwide. Pollution disproportionately kills the poor and vulnerable.

CMMI /Innovation Center

TALKING POINTS:

- Innovation in health care should be designed for the people it serves; its success should be measured by how well it improves health, experience, and affordability of care.
- The Innovation Center, with its federal and community partners, has started building the foundation toward a health system that achieves equitable outcomes through high-quality, affordable, person-centered care.

New Coordinated Care Models

- The Innovation Center has announced the:
 - Enhancing Oncology Model (EOM), which aims to bring enhanced services and coordinated care to people with cancer; and
 - The redesigned (ACO REACH) Model, which aims to increase access to team-based, coordinated care, and improve the beneficiary experience, especially for underserved populations

New Drug Models

- This year, I selected three new models for testing by the CMS Innovation Center to help lower the high cost of drugs, promote accessibility to life-changing drug therapies, and improve quality of care. This report responds to President Biden’s Executive Order 14087, “Lowering Prescription Drug Costs for Americans,” which complements the historic provisions in the Inflation Reduction Act of 2022 (IRA) that will lower prescription drug costs.

QUESTIONS:

Executive Order

Q: Why is CMS maligning drugs that rely on surrogate end points – and the accelerated pathway used by FDA? The drugs approved under this process clearly show pre-clinical benefit.

- The Accelerating Clinical Evidence Model does not change the FDA accelerated approval process. The model simply aims to incentivize timely completion of confirmatory trials.
- Completion of confirmatory trials is important so that everyone has the benefit of better understanding the value of these accelerated approval drugs.
- The Accelerating Clinical Evidence Model will not change FDA’s role in determining and assessing whether a drug has met the drug approval standard or whether a confirmatory trial confirms clinical benefit.

Q: Congress just updated the FDA user fee law. Can you tell me more about how CMS proposes to define “too long” for a confirmatory clinical trial to conclude?

CMS will cooperate with the FDA as we develop this model and will clearly define expectations regarding the completion of clinical trials.

Q: Many plans have copayments less than \$2 on generic drugs currently. Won't this just create upward pressure on all plans to charge \$2, thus increasing copays for beneficiaries?

- This model would encourage plans to expand their current low copay drug offerings and provide beneficiaries access to a standardized list of generics (with copays of no more than \$2) across participating plans. Historically market dynamics have shown Part D sponsors want to offer competitive cost-sharing.

ACO REACH

Q: Concerns have been raised regarding the participation of organizations with known histories of fraud and abuse in the ACO REACH Model. How will CMS prevent these organizations from engaging in fraud and abuse under the ACO REACH Model?

- CMS conducts a comprehensive set of vetting, monitoring, auditing, and analytic activities under the ACO REACH Model aimed at protecting beneficiaries, and the fiscal health of the Medicare program. Each model participant is required to cooperate with CMS's monitoring and auditing activities, and each must require its downstream providers and suppliers to cooperate with those activities as well.
- Failure to comply with model requirements is addressed through a set of escalating remedial actions that include placement on a corrective action plan or, in select instances, termination from the model. In addition, CMS may refer possible violations of federal laws by model participants to other federal agencies, such as the Department of Justice.

Q: Are any of the REACH ACOs health insurers or Private Equity / Venture Capital backed? If so, how many?

- Based on available data, CMS estimates that less than 10% of REACH ACOs are affiliated with a parent organization that also operates health insurance plans.
- To bring greater transparency to this program, CMS committed to publicly releasing ownership data on its participants and did so earlier this year.
- CMS also made requirements of participants' governing boards, ensuring 75% of the board is made up of doctors and health care providers and requiring participation by beneficiaries and their advocates.

Q: Participants in the Global and Professional Direct Contracting Model were able to transition to ACO REACH without having to go through the applicant screening process. Did CMS review existing participants against the new applicant screening process?

- To be able to transition to the ACO REACH Model, Global and Professional Direct Contracting Model participants were assessed on the status of their compliance the current model requirements.
- They were also required to submit additional documentation consistent with what CMS required of ACO REACH Model applicants, specifically ownership, leadership, and governing board documentation that was used as part of a comprehensive vetting process.

Conscience Protections

TALKING POINTS:

- HHS has long enforced federal conscience and religious nondiscrimination laws for many decades.
- HHS will continue to follow the law and enforce it, which importantly includes religious freedom and conscience laws.

QUESTIONS:

Q: Does OCR's recent reorganization mean OCR will abandon enforcing conscience laws and religious freedom protections?

- No. HHS will continue to follow the law and enforce it, which importantly includes religious nondiscrimination and conscience laws.
- The reorganization re-integrates the Office for Civil Rights' expertise in protecting conscience and the free exercise of religion into the overall civil rights responsibilities of the division to bridge an unnecessary separation between these authorities.
- The change restores a holistic approach to civil rights enforcement while also providing more effective use of available staff expertise and resources.

Q: Will the Conscience NPRM be impacted by this reorganization?

- No, the reorganization will not impact OCR's work on the Conscience NPRM.
- This NPRM proposes to restore the longstanding process for the handling of conscience complaints and provide additional safeguards against conscience and religious discrimination.
- OCR is currently reviewing comments received earlier this month.

Q: What is the breakdown of OCR's complaints by authorities?

- OCR's caseload has multiplied in recent years. In CY 2021, OCR received approximately 51,280 complaints, 27% alleged violations of civil rights, 7% alleged violations of conscience/religious freedom (either singularly or in combination with other civil rights allegations), and 66% alleged violations of health information privacy and security laws. HIPAA violations make up the majority of complaints received by OCR and this will only continue to grow.

Q: What outcomes does HHS hope to achieve through this realignment?

- OCR enforces 55 statutory authorities. OCR realigned the Division's activities to better meet its statutory mandates, enforce the law and be responsive to the growing needs of the public in health information privacy, data, and cybersecurity, conscience protections, and civil rights. These changes move OCR from a more siloed operation to one that utilizes the agency's skill set and resources more effectively. Specifically, OCR reorganized the responsibilities of the current Health Information Privacy, Operations and

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Resources, Civil Rights and the Conscience and Religious Freedom divisions into new functional crosscutting areas: for Policy, Strategic Planning, and Enforcement where staff work in their areas of expertise based on skill set to drive greater implementation and enforcement of the law.

Program Information

BACKGROUND:

OCR Reorganization:

- On February 27, 2023, OCR issued a reorganization.
- Through this change OCR will reorganize the responsibilities of the current Health Information Privacy, Operations and Resources, Civil Rights and the Conscience and Religious Freedom divisions into new functional crosscutting areas: Policy, Strategic Planning, and Enforcement where staff will work in their areas of expertise based on skill set to drive greater implementation and enforcement of the law.
 - The Policy Division will be focused on rulemaking and guidance for OCR legal authorities integrating staff from Civil Rights and Conscience and Religious Freedom Divisions.
 - The Enforcement Division will integrate case management and the 8 regions, as well as enforcement staff from Civil Rights, Conscience and Religious Freedom and Health Information Privacy under a standalone Division dedicated to enforcement work.

Conscience NPRM

- On December 29, 2022, OCR announced a Notice of Proposed Rulemaking (NPRM), entitled *Safeguarding the Rights of Conscience as Protected by Federal Statutes*, which proposes to restore the longstanding process for the handling of conscience complaints and provide additional safeguards to protect against conscience and religious discrimination.
- In 2019, OCR issued a regulation that provided broad definitions, created new compliance regulations, and created a new enforcement mechanism for a number of statutes related to the conscience rights of certain federally funded health care entities and providers.
- The 2019 Final Rule was held unlawful by three federal district courts.
- In light of these court decisions, and consistent with the Administration's commitment to safeguard the rights of federal conscience and religious nondiscrimination while protecting access to care, this NPRM proposes to partially rescind the Department's 2019 rule while reinforcing other processes previously in place for the handling of conscience and religious freedom complaints.
- The public comment period closed on March 6, 2023.

COVID Supplemental Funding Balances

(Dollars in Billions)

Supplemental	Enacted	Remaining Balance	Percent Remaining
Coronavirus Preparedness and Response Supplemental	\$6.5	\$0.5	7%
Families First Coronavirus Response	\$1.3	\$0	0%
Coronavirus Aid, Relief, and Economic Security	\$142.5	\$3.1	2%
Paycheck Protection Program and Health Care Enhancement	\$100	\$7.2	7%
Coronavirus Response and Relief	\$73.8	\$1.3	2%
American Rescue Plan	\$160.5	\$17.3	11%
Total Supplemental Funding	\$484.6	\$29.5	6%

TALKING POINTS:

- Since 2020, we've delivered over 294 million vaccines, collaborated with the U.S. Postal Service to distribute more than 670 million at-home tests, administered over 22 million vaccine doses at our HRSA-supported health centers, and continuously reviewed, updated, and communicated new guidance to the public and our health care industry partners.
- As of March 6, HHS has obligated 94% of the COVID supplemental funding received; that's over \$455 billion to purchase vaccines and other critical medicines, reimburse providers for COVID care, distribute tests, conduct research, and otherwise protect the Nation's health.
- HHS has approximately \$29.5 billion left unobligated in COVID supplemental funding – only 6% of the of total we've received – with the remainder planned to support critical projects and in the process of execution.
- HHS's goal for these balances is the same goal we have for the FY 2024 budget: move forward from the COVID-19 pandemic, and look to the future by investing heavily in pandemic preparedness. We must do everything we can now to be ready for the future.

QUESTIONS:

Q: You'll be ending the Public Health Emergency for COVID in May. Will you be returning COVID funding balances to Congress now that there's no emergency?

- All balances are intended for critical, ongoing activities such as, monitoring the safety and efficacy of vaccines, conducting multi-year research and development on new medical countermeasures, and sustaining stockpiled countermeasures and protective equipment for the next emergency.
- These investments also support our public health preparedness infrastructure. CDC continues to invest supplemental funding at the federal, state and local levels to build our nation's capacity to respond to COVID-19, but also for other, future threats.

- We've seen a consequential impacts from the dollars spent to far on the response. Since 2020, we've delivered over 294 million vaccines, collaborated with the U.S. Postal Service to distribute more than 670 million at-home tests, administered over 22 million vaccine doses at our HRSA-supported health centers, and continuously reviewed, updated, and communicated new guidance to the public and our industry partners.

Q: COVID revealed the ways in which the United States was not ready for an infectious disease threat of this magnitude. What are you doing to ensure we can be better prepared for future biological threats and infectious disease outbreaks?

- We need to do more to prepare against potential biological threats – the question is “when”, not “if” the next pandemic threat will emerge.
- That's why my FY 2024 budget includes a \$20 billion plan to transform the way we prepare for and respond to pandemic and other biological threats. The looming avian influenza threat is exactly the kind of threat we could have been preparing for in advance – but we need funding to do so.
- The Budget also includes discretionary investments to preparedness complementary to the mandatory proposal. This includes \$400 million in new funding at ASPR to continuously invest in long-term pandemic preparedness capabilities, over \$1 billion for BARDA, \$995 million for the Strategic National Stockpile, and other strategic investments at CDC, FDA, and NIH.
- The budget also includes a suite of legislative proposals intended to give HHS and its agencies better authorities to prepare for and respond to emergencies. We learned many lessons during COVID, mpox, and other recent emergencies, but we need Congress's help to implement these changes.

Q: If you have almost \$30 billion dollars left, and my hospital that your agency denied Provider Relief Funds to is on the verge of closing due to lack of funds—why can't you re-open the PRF and give my hospital the funding it needs to stay open?

- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding —96% of all funding, with the remaining 4% in the process of being executed.
- HHS has allocated resources to reimburse health care providers for the cost of COVID-related health care through the Provider Relief Fund program. HRSA conducts a thorough, multi-step process to evaluate and verify provider claims and requests for reconsiderations. While most funds have been obligated, in some instances, HRSA's process is not yet complete. Congress made these funds available until expended.
- HHS obligates PRF funds as payments are made.

Q: Why are you using PRF dollars for vaccines and testing if you have \$30 billion left?

- All Covid supplemental funding has been allocated in alignment with the purposes of the appropriations. While approximately \$30 billion is unobligated, all of this amount is already allocated to critical needs, mostly to support actively ongoing projects, including for Provider Relief Fund payments. All remaining funding cannot be obligated at once – many of the ongoing projects, like clinical trials, require us to continue to provide funding over time.

Q: If you have \$30 billion why did you close the Uninsured Program?

- HHS is committed to doing everything it can to ensure that the uninsured can receive the lifesaving care, vaccines, and therapeutics that they need. The funding for the uninsured program has been exhausted, a fact we alerted Congress to many times as we requested additional COVID supplemental funds
- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding, which is nearly all of the PRF funding we received.
- While we do have \$30 billion in unobligated funding, all of this funding is allocated for critical needs. Additionally, not all unobligated funding would be legally available to support the Uninsured Program.
- Further, my administration is committed to insuring the un- and under-insured in this country, which is why the national uninsured rate hit an all-time low of 8% in 2022. To this same end, I call on the remaining 10 states to follow North Carolina's lead and expand their Medicaid programs.

Q: COVID-19 Tests.gov website shut down in 2022 due to a lack of funds, but now you have \$30 billion. Please explain this to me?

- Our groundbreaking partnership with the US Postal Service distributed more than 670 million at-home COVID-19 tests to Americans all across the country. By making tests freely available through multiple means, as well as life-saving vaccines and therapeutics, we've done everything we can to tackle the COVID-19 pandemic.
- HHS has approximately \$29.5 billion left unobligated in COVID supplemental funding – only 6% of the of total we've received – with the remainder planned to support critical projects and in the process of execution.
- HHS could not continue to distribute tests through covid.gov/tests with limited funding. The HHS response to COVID-19 is broader than just providing free tests, and we had to allocate resources to where they were needed most.

Program Information

Remaining COVID balances support critical, ongoing activities, many of which were always planned to be multi-year. Some of the large balances include:

- **CDC**: \$4 billion unobligated and in process for execution across multiple activities such as:
 - Ongoing vaccine safety and effectiveness monitoring and vaccine data systems
 - Creating a robust national genomic sequencing infrastructure, to help place the US Public Health System in a position to respond rapidly to emerging threats
 - The Infectious Diseases Rapid Response Reserve Fund, which will support rapid response to future threats as Congress intended
- **IHS**: \$1.6 billion remains unobligated with IHS-operated health care programs, where funds directly support the provision of daily health care
- **ASPR**: \$6 billion unobligated and in process for execution across multiple activities such as:
 - Sustainment of the Strategic National Stockpile COVID-capabilities through FY 2025
 - Ongoing development of domestic supply chain and medical industrial capabilities for rapid response in a pandemic, such as warm-basing and manufacturing capacity expansions for personal protective equipment and other key medical supplies
 - Advanced research and development of therapeutics, vaccines, and diagnostics
- **Provider Relief Fund**: \$6.8 billion unobligated, which includes funding for claims payments for care given to the uninsured population.
- **ARP Testing Funds**: \$8.3 billion unobligated and in the process of execution to support:
 - Surveillance, state and local public health department support, laboratory enhancements, and technical assistance for healthcare personnel
 - Research and ongoing clinical trials, which HHS has ethical obligations to wrap up in a responsible manner
 - Media campaigns to ensure that our effective and safe COVID-19 treatments are available and accessible to everyone.

COVID - Long COVID

TALKING POINTS:

FY 2024 Budget Talking Points

- The Administration continues to invest in delivering high-quality care for individuals experience Long COVID, making services and supports available, and advancing the nation's understanding of Long COVID.
- To help improve Long COVID care, the budget proposes \$130 million in new resources to HRSA to:
 - Fund Long COVID Integrated Diagnostics and Care Units, which will provide integrated multispecialty evaluation and care for uninsured patients with Long COVID, including through telemedicine.
 - Support Provider Training, Capacity Building and Consultation, serving to provide primary care providers with the latest knowledge about Long COVID diagnostics and treatment.
- Additionally, the FY 2024 budget invests \$19 million, an increase of \$9 million, to continue AHRQ's work to ensure health care delivery systems are prepared to provide patient-centered, coordinated care. Long COVID cases can be complex, affecting multiple organ systems and touch multiple specialties.

General Long COVID Talking Points

- Most people who have COVID-19 recover quickly and completely, but some people continue to experience new or re-occurring symptoms or conditions for weeks, months or even years after the initial infection.
- We must build on the lessons learned from other infection associated chronic illness, such as ME/CFS or dysautonomia.
- The end of the declared Public Health Emergency will not signal the end of the COVID-19 pandemic. Long after the more immediate effects of the pandemic, the longer-term impacts on the health of the nation will continue for years to come. The scale of Long COVID morbidity and mortality and the breadth of its clinical manifestations represent an unprecedented, but not insurmountable, challenge.
- Pandemic preparedness must include planning for post-infectious chronic illness.
- To meet our public health goals there must be continued investment at the federal and community level to meet people in need where they are, and to provide support and services to help them live their healthiest lives.

Federal Government Response to Long COVID

- The U.S. government has been conducting research on Long COVID since 2020 and providing care for individuals with Long COVID within federally supported healthcare systems such as the Veterans Health Administration, Federally Qualified Community

Health Centers, Certified Community Behavioral Health Clinics, and the Indian Health Service.

- o Milestones in the U.S. government response include a call for action on Long COVID in the [Presidential Health Equity Task Force](#), Final Report and Recommendations, released in October 2021, [announcement of the landmark RECOVER study in February 2021](#), and inclusion of Long COVID in the [National COVID-19 Preparedness Plan](#) in March 2022.
- o In April of 2022 President Biden issued the [Memorandum on Addressing the Long-Term Effects of COVID-19](#) instructing the Secretary of Health and Human Services to begin coordinating a government-wide response. Part of that response resulted in the publication of two reports in August 2022. These reports were the product of collaboration among 14 federal departments and were a significant step in orchestrating a government wide response. Together, these reports use a whole-of-government approach and call on the power of public-private partnerships to provide relief for those affected by Long COVID.
- o The [Services and Supports for Longer-Term Impacts of COVID-19](#) Report outlines over 200 federally funded support and services that may be available for individuals experiencing the longer-term effects of COVID-19 in the areas of Long COVID and associated conditions, mental health, substance use, and bereavement.
- o The [National Research Action Plan on Long COVID](#) provides an overview of current U.S. government conducted or funded research and proposes a comprehensive and equitable research strategy to inform our national response to Long COVID.

RECOVER Initiative Talking Points:

- NIH launched the Researching COVID to Enhance Recovery (RECOVER) initiative in December 2021 to define the clinical symptoms, long-term outcomes, underlying biology of Long COVID, and safe and effective therapeutic and preventive interventions.
- NIH RECOVER built the world's largest, most diverse clinical cohort of Long COVID patients across the lifespan. The initiative is patient-centered and is unparalleled in scope, scale, and speed, with integrated analyses of EHR and other real-world data.
- We have learned vital information from RECOVER, including the clinical spectrum in adults and children, risk factors for developing Long COVID or new-onset conditions, the impact of variants and vaccination, and symptom profiles that will enable clinical practitioners to screen for Long COVID.
- RECOVER expects to launch a suite of clinical trials this year that will delve deeper into key symptoms and explore how the virus survives and leads to long-term symptoms. These studies will also help us to understand the underlying biology so we can fine-tune interventions moving forward.

QUESTIONS:

Q: Why haven't we seen results from RECOVER yet? When will those be publicly available?

- RECOVER is moving at an unprecedented quick pace for a study with the comprehensive national scale required to understand and treat a new syndrome. RECOVER is a longitudinal, multifaceted effort which has already yielded results identifying the clinical symptoms in children and adults, risk factors for PASC, the impact of variants and vaccination on disease. In addition to these successes, a suite of clinical trials is expected to be launched in summer 2023 to focus on the symptoms that are most burdensome to daily life and to look at disease mechanisms. Like any clinical trial, we would expect initial results from clinical within a few years, however longitudinal studies inherently require several years if not decades to complete.

Q: When will clinical trials for Long COVID begin? Why is it taking so long?

- To achieve the depth and breadth required to get the answers patients need, we did a great deal of the work on the front end—like developing master protocols—based on everything we know. This is helping us to get to answers faster with data we can depend on and use, and treatments patients can trust.
- RECOVER is launching multiple randomized, comparator-controlled clinical trials for which site recruitments are underway. Through the balance of this year, RECOVER will be testing candidate therapies for symptoms described by patients as being most burdensome. Those protocols are now posted to clinicaltrials.gov.

Q: What is HHS doing to respond to Long COVID?

- Nearly a year ago the Biden Administration issued the Memorandum on Addressing the Long-Term Effects of COVID-19 which tasked me with organizing the Government-Wide Response to the Long-Term Effects of COVID-19. Including the issuance of two reports:
 - o **The Services and Supports for Longer-Term Impacts of COVID-19 Report (Services Report).** The Services Report outlines over 200 federally funded supports and services for individuals experiencing the longer-term effects of COVID-19 in the areas of Long COVID and associated conditions, mental health, substance use, and bereavement.
 - o **The National Research Action Plan on Long COVID (the Research Plan).** The Research Plan outlines over 70 active research programs on Long COVID, including NIH's RECOVER and CDC's INSPIRE, which have helped contribute to the hundreds of publications, with more on the horizon. The Research Plan also proposes a comprehensive and equitable research strategy to inform our national response to Long COVID.
- Starting work in earnest in mid-2021, the U.S. government continues to lead and make advancements in research and provide resources to those affected by Long COVID,

recognizing much more must be done to support people experiencing Long COVID and associated conditions.

Q: I hear from constituents that they go to the doctor and nobody believes them and they can't get care. What is HHS doing to fix this?

- Unfortunately, this occurs. While there are many compassionate and competent healthcare providers finding and caring for Long COVID patients, it is a new entity and awareness needs to increase both among the citizenry and healthcare professionals.
- Our whole-of-government coordination efforts to address the long-term effects of COVID-19 has prioritized listening to and learning from those with lived experience, so we can accelerate understanding and breakthroughs together.
- Admiral Levine, the Assistant Secretary for Health, has met with Long COVID patients, providers, and researchers to hear more about their experiences and how we can harness the federal governments strengths to address their most pressing calls for action. This includes supporting provider education efforts through CDC, working with provider organizations and external groups.
- In November of last year HHS released the Health+ Long COVID Report to better understand the complexities of Long COVID and cultivate creative patient-driven solutions. The Health+ Long COVID Report was commissioned by HHS and produced by an independent third-party design and research firm and includes opportunity areas where clinicians, patient advocacy organizations, public health professionals and leaders in government can improve accessibility to support and services through practical solutions.
- HHS is also working to investigate and promote evidence-based care models. For example, we are investigating how health care systems can utilize telehealth to reach patients in rural communities; how telementoring can connect expert clinicians to primary care practices; and how we advance the development of multispecialty clinics to provide complex care.
- This work would fund institutions across the country that bring together leading researchers and care providers across the full care continuum – including hospitals, health centers, long-term care services and supports, and other providers – and promote the implementation of new evidence into care, especially for disproportionately affected populations.

Q: We are now in the 4th year of the pandemic, why don't we know more about Long COVID already?

- Research is rapidly emerging and every week the scientific and medical community around the world is getting a better understanding of the various Long COVID endotypes and the differing pathophysiology; distinctions necessary to develop diagnostics and therapeutics.

- Long COVID is not one entity, so dissecting it into understandable and manageable components will take time.
- Research is establishing clinical criteria for diagnoses and elucidating possible pathophysiologic mechanisms to inform laboratory and other test development and other diagnostic strategies.
- This foundational research is already providing valuable insights and will inform Long COVID clinical trials, which will help find treatments for those suffering from its effects.
- The U.S. government has a leading role in this Long COVID research through the work it conducts itself, including research in government-led health systems such as the VA and Indian Health Service; by funding private research; and by coordinating efforts across public and private entities.
- The National Research Action Plan lays out the higher level approach to getting this work done.

Q: It seems like HHS is blowing Long COVID out of proportion to scare people-I understand that data from CDC shows that Long COVID is not real.

- [Research suggests between 5% to 30%](#) of those who had COVID-19 struggle with Long COVID symptoms 30 days after their acute infection.
- On December 1, in JAMA Network Open, an academic group of CDC INSPIRE grantees published an interim analysis of overall well-being 3 months after a positive test for SARS-CoV-2 among an initial adult cohort of 1000 (of the estimated final cohort of 6000) in an multicenter prospective longitudinal cohort study.
- After statistical adjustment, comparing baseline and overall self-reported well-being at 3 months, improvements were greater in the COVID-19 group vs the negative group for social participation, especially among those aged 18 to 34 years and those presenting to ambulatory care for testing. Changes in other domains were not significant.
- The results of the study are preliminary, introduce the INSPIRE study, and demonstrate the importance of a control group. The findings highlight the potential widespread impact of the pandemic on our overall health, including the lesser-tracked emotional, social, and mental aspects, alongside the highly recognized physical effects.
- It is important we recognize that these findings do not negate the existence of Long COVID, or call into question the reality of the patient experience. Infection associated chronic illness is not new. There is substantial ongoing research on infection-associated chronic conditions and other diseases that may have infectious origins, including dysautonomia and ME/CFS. It is important to build on this research to achieve a deeper understanding of Long COVID and guide us to effective responses that protect the nation's long-term health.

Q. I continue to read in the news that people with Long COVID are being denied Social Security Disability Insurance. What is HHS doing to ensure SSA is working to provide economic relief for those who have become disabled or unemployed due to Long COVID?

- I defer to my colleagues at the Social Security Administration to provide more information on Social Security Disability Insurance (SSDI). However, we are working with them closely to move forward.
- I do want to share that separate from SSDI, HHS worked with the Department of Justice to publish guidance on Long COVID as a disability. Long COVID may be considered a disability under civil rights laws, which can protect people from discrimination.
 - o Titles II (state and local government) and III (public accommodations) of the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973 (Section 504), and Section 1557 of the Patient Protection and Affordable Care Act (Section 1557). Each of these federal laws protects people with disabilities from discrimination.

COVID - Mandates

TALKING POINTS:

- Time and time again, we have seen that the vaccine is both incredibly safe and effective against severe disease and death from COVID-19.
- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.
- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - o 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.

If asked about foreign national mandate:

- Evidence continues to show that vaccination does offer substantial protection against severe infection and hospitalization, and vaccines do offer some protection against infection.
- Having fully vaccinated travelers reduces the impact on the US public health and health care system.
- That said, the Administration is engaged in ongoing discussions about this policy.

QUESTIONS:

Q: Why is there still a Vaccine Mandate in place for health care workers when the PHE is ending May 11th?

- One way to prevent health care workforce shortages is to ensure they are healthy.
- The staff vaccination requirement for all Medicare and Medicaid certified providers has been enforced in all states since February 20, 2022. To date, most providers surveyed by states have been found to be in substantial compliance with this requirement.
- The requirements in the Omnibus COVID-19 Health Care Staff Vaccination interim final rule with comment will expire on November 5, 2024 if CMS does not take additional action.
- That said, the Administration is engaged in ongoing discussions about this policy.

Q: Why is there still a Vaccine Mandate for Head Start when there is a shortage of child care access for working families?

- One way to prevent health care workforce shortages is to ensure they are healthy.
- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.

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- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.
- That said, the Administration is engaged in ongoing discussions about this policy.

Q: Why did CDC close schools?

- This Administration prioritized opening schools for the critical role they play in not only educations, but support for children through school meal programs and social, physical, behavioral, and mental health services.
- Three weeks after this Administration took office, CDC released guidance that served as a roadmap for how schools could open safely.
 - Prior to the release of this guidance only 46 percent of schools were offering full-time instruction. Just a few short months after, over 60 percent of schools offered full-time instruction and by the fall of that year, 95 percent of schools offered full-time instruction.

Q: Why did CDC send its school guidance to the teacher's union?

- When developing guidance and recommendations, CDC often engages with organizations and groups that are impacted. The agency does so to ensure recommendations are comprehensive, consider stakeholder needs and concerns, and are feasible to implement.
- These informative interactions result in beneficial feedback for final revisions to promote clarity, completeness, and usability.
- For the development of the school guidance, CDC had close engagement with the U.S. Department of Education and sought input from 50+ different organizations and stakeholders—including teachers, superintendents and parents to discuss experiences, challenges, and lessons learned in implementing prevention strategies for infectious diseases in K-12 schools.

Q: What is CDC's role in setting vaccine mandates?

- CDC collects data on the effectiveness of vaccines and the uptake of those vaccines in population groups (general public, healthcare workers, children, etc)
- CDC also provides information to the general public and policymakers about the state of infectious disease outbreaks (influenza, COVID-19, mpox)
- CDC makes recommendations about who should be vaccinated and when based on the science
- CDC makes this information available to policymakers who are ultimately responsible for making decisions about vaccine requirements. Policymakers can use this information to make decisions about the populations they are responsible for protecting.

Q: Now that we know the vaccines do not prevent transmission, will you go on the record to acknowledge that there is no scientific rationale justifying a vaccine mandate for COVID-19?

- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.
- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.
- That said, the Administration is engaged in ongoing discussions about these policies.

COVID - Misinformation

TALKING POINTS:

- Bridging the health equity divide has been a critical component of the COVID-19 pandemic response. Americans in rural, urban, and tribal areas must have access to public health interventions and we are actively finding and closing these gaps.
- HHS is working to reach people where they are, but disinformation and misinformation often reaches them faster.
- We needed trusted messengers to help. Americans don't always want to hear from a government official, sometimes they want to hear from somebody in their local pharmacy or their local pediatrician.
- HHS works with our Pharmacy Partners and our We Can Do This campaign to use trusted community messengers to answer questions and provide accessible information about vaccines.
- It takes all of us to tackle disinformation and misinformation.

Questions:

Q: What is the impact of misinformation regarding vaccines?

- Vaccination coverage has dropped a total of 2 percentage points since the start of the pandemic for kindergartners. In real terms, this **means 250,000 kindergartners not getting their vaccinations.**
- To stop misinformation from eroding public trust in vaccines, CDC will continue its work with local partners and trusted messengers to improve confidence in vaccines among groups placed at higher risk, including racial and ethnic minorities and with parents of very young infants and expectant parents.

Q: While serving in this Administration, have you, or any of your staff, ever asked a technology company to take down an American's social media post regarding the pandemic response?

- Thank you for the question. Because there is pending litigation, I'm not going to get into any specifics on that today. But what I will say is that COVID-19 misinformation spread online is a serious issue that has real public health impacts.

Q: What is HHS doing to combat misinformation?

- HHS has undertaken a campaign which has activated partnerships, digital outreach, influencers, and paid media to reach Americans where they are, with a focus on outreach around new COVID-19 vaccine authorizations.
- The campaign has hosted over 400 COVID-19 vaccine educational booths and vaccine pop-up clinics in more than 90 cities. HHS has also launched the COVID-19 community corps, a network of nearly 20,000 community leaders and volunteers who serve as trusted local voices.

COVID – Origins

COVID – Origins (China)

TALKING POINTS:

- For more than two years, China has blocked international investigators and members of the global public health community from accessing information related to COVID-19 origins. This is unacceptable – and we must not let this prevent us from getting answers.
- The fact is that the Chinese government hasn't been transparent enough. For us to be able to get to the bottom of this, we need critical information about the origins of this pandemic that exists in the People's Republic of China.
- Yet from the beginning, government officials in China have worked to prevent international investigators and members of the global public health community from accessing it.

QUESTIONS:

Q: Will this Administration hold China accountable for obstructing efforts to investigate covid origins?

- The fact is that the Chinese government hasn't been transparent enough. This is unacceptable – and we must not let this prevent us from getting answers.
- We will continue to work with partners around the world to press China to fully share information and to cooperate with international investigations.
- Getting to the bottom of the origins of COVID-19 remains a priority for this Administration.

Q: Do you support calls to sanction China until it fully complies with international investigations?

- I'm not here today to opine on foreign policy. But what I will say is that the Chinese government hasn't been transparent enough on this issue – and that is unacceptable.

COVID – Origins (IC Assessments)

TALKING POINTS:

- President Biden has directed, repeatedly, every element of our intelligence community to put the effort and resources behind getting to the bottom of the origins of COVID-19.
- There are a variety of views on this issue in the intelligence community. Some elements have reached conclusions with varying levels of confidence on one side, some on the other, and others have said they don't have enough information.
- Valuable, bipartisan work remains to be done to address the Chinese government's lack of transparency and ensure investigators can access this critical information about the origin of COVID-19, so we can better understand how to prevent future pandemics.

QUESTIONS:

Q: Do you think that the “lab leak” theory is misinformation or a conspiracy theory?

- I think it’s important to be precise here. On the one hand, some elements of the intelligence community have concluded, with varying degrees of confidence, that the coronavirus may have escaped from a lab. However, I am not aware of any evidence that the coronavirus was intentionally released as a biological weapon.
- There is no doubt that this is an important question. That’s why this Administration has, from the beginning, prioritized efforts to get to the bottom of the origins of COVID-19.

Q: Both the Energy Department and the FBI have now concluded that the coronavirus likely originated from a lab leak. What is HHS’s current assessment?

- We don’t currently know the precise origins of the pandemic.
- The scientific evidence to date suggests that the virus is the result of normal viral evolution and not the result of genetic modification in a lab.
- The question that remains is if researchers working with infected bats or samples accidentally became infected and unintentionally spread it to others.
- There is no hard evidence to indicate that this happened, but certainly, it’s something we want to know. Importantly, that will require cooperation from China and other countries to get to that information.

Q: Did Dr. Fauci tell the truth about Covid origins?

- Political attacks on public health officials like Dr. Fauci who have spent their careers saving lives are completely counterproductive.
- Dr. Fauci has said he agrees with the President that we need to get to the bottom of how COVID originated.
- I’ll let Dr. Fauci speak for himself. We have been grateful for his wisdom and advice during the COVID response, and we have all been very clear that we will use every tool to figure out what happened here.

COVID – Origins (EcoHealth/Gain of Function Research)

TALKING POINTS:

- Research on infectious diseases helps develop vaccines and treatments and needs to be done safely, securely, and transparently -- here and abroad.
- HHS takes its responsibility to be a good steward of taxpayers’ investment in biomedical research seriously.
- To that end, last year HHS tasked the National Science Advisory Board for Biosecurity (NSABB) to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.

- The NSABB issued its final report and recommendations earlier this month. HHS, and our interagency partners, will consider this report as part of a broader government-wide review process, which aims to effectively balance science and security, while safely enabling critical lifesaving research.

QUESTIONS:

Q: Did the NIH through its EcoHealth grant fund gain-of-function research in the Wuhan Institute of Virology (WIV) that resulted in COVID-19?

- No. NIH has never approved any research that would make a coronavirus more dangerous to humans.
- The research we supported in China, where coronaviruses are prevalent, sought to understand the behavior of coronaviruses circulating in bats that have the potential to cause widespread disease.
- The body of science reported—including the bat coronavirus sequences published in the scientific literature—showed that the viruses studied at WIV under the NIH grant were evolutionarily quite distant from SARS-CoV-2 and could not have been the source of the COVID-19 pandemic.
- And importantly, because of similar research to understand coronaviruses, we were able to move swiftly to develop vaccines against SARS-CoV-2 and save lives.

Q: Why does HHS support research in China at all?

- HHS supports research to better understand the characteristics of animal viruses that have the potential to spill over to humans and cause widespread disease.
- We must collaborate with researchers in other countries where these sorts of viruses are prevalent because once a virus spreads to humans, it is not contained by geographical boundaries.
- Infectious outbreaks have happened throughout history. Let's not forget the SARS epidemic in 2003 that was traced to civets as an intermediate host or the H1N1 flu pandemic in 2009 that originated from pigs.
- The body of research on pathogens and infectious diseases is what has made it possible for the U.S. government to move so quickly to get a COVID-19 vaccine in an unprecedented timeframe of just 11 months. Countless lives have been saved as a result.

Q: What is this Administration doing to ensure taxpayers are not funding risky biomedical research that could lead to another public health crisis?

- In February 2022, NIH tasked the National Science Advisory Board for Biosecurity (NSABB) to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.
- In March 2023, the NSABB issued its final report containing its findings and recommendations.
- These findings and recommendations will inform ongoing USG policy deliberations.

Q: The HHS OIG recently found that NIH did not effectively monitor or address EcoHealth’s compliance with grant requirements, when it was conducting risky research at the WIV. Dr. Larry Gostin, who has advised this White House on the pandemic response, called the OIG report a “damning indictment of NIH.” Do you agree?

- We respect the OIG’s findings and have taken action to address their recommendations.
- HHS takes its responsibility to be a good steward of taxpayers’ investment in biomedical research seriously. We are committed to conducting oversight of the research we fund to ensure safety, security, and responsible conduct.
- That’s why we charged the NSABB to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.
- Additionally, recipients of NIH awards are accountable for ensuring the stewardship of federal funds and must comply with all applicable federal statutes, regulations, policies, and institutional requirements.

COVID - OTC Tests

TALKING POINTS - MEDICARE:

- CMS prioritizes supporting beneficiary access to the care they need and after the end of the public health emergency (PHE).
- Medicare beneficiaries can continue to access medically necessary COVID-19 polymerase chain reaction (PCR) tests and antigen tests performed by a laboratory at no cost to them when the test is ordered by a physician or non-physician practitioner and some Medicare Advantage plans may continue to provide coverage for these tests as a supplemental benefit.
- By law, Medicare does not generally cover over-the-counter (OTC) services and tests. Current access to free OTC COVID-19 tests will conclude at the end of the PHE. When the demonstration was implemented, it was announced that the demonstration would end at the end of the PHE.

TALKING POINTS – OTHER PLANS:

- The requirement to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end at the end of the PHE - coverage may continue if plans choose to continue to include it, which we are encouraging them to do.

QUESTIONS:

Q: Will CMS be extending the Medicare OTC demonstration?

- When CMS implemented this demonstration, we stated that CMS would pay claims for over-the-counter COVID-19 tests starting on or after April 4, 2022, through the last day of the COVID-19 public health emergency, which the President announced would be May 11, 2023.
- After the end of the COVID-19 PHE, Medicare beneficiaries can continue to access medically necessary COVID-19 polymerase chain reaction (PCR) tests and antigen tests performed by a laboratory at no cost to them when the test is ordered by a physician or non-physician practitioner.
- Some Medicare Advantage plans may cover and pay for at-home over-the-counter COVID-19 tests as a supplemental benefit in addition to Medicare Part A and B benefits, so consumers enrolled in Medicare Advantage plans should check with their plans to see if they offer this benefit separate from coverage for all Part B enrollees under the demonstration.

Q: What about Medicaid coverage?

- Under the American Rescue Plan Act of 2021, State Medicaid programs are required to cover FDA-authorized home diagnostic and screening tests for COVID-19 for most

Medicaid beneficiaries without cost-sharing, until the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE.

- Because Medicaid coverage parameters may vary by state, people dually eligible for Medicare and Medicaid and who are eligible for full Medicaid benefits should contact their state Medicaid agency for information regarding the specifics of Medicaid coverage for at-home COVID-19 tests.

Q: What about private insurance coverage?

- The requirement for group health plans and health insurance issuers offering group or individual health insurance coverage to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end at the end of the PHE. However, coverage may continue if plans choose to continue to include it. We are encouraging private insurers to continue to provide such coverage going forward.

COVID - Vaccine Safety

TALKING POINTS:

- Time and time again, we have seen that the COVID-19 vaccines are both incredibly safe and effective against severe disease and death from COVID-19.
- Vaccination remains the safest and most dependable strategy to build immunity. Most adverse events following vaccination are mild and resolve quickly, such as pain at the injection site and fever. Serious adverse events are rare.
- That said, COVID-19 vaccine safety remains a top priority for HHS, and reports of health problems are taken seriously. CDC, FDA and its partners use several complementary vaccine safety systems to monitor for adverse events.
- We are dedicated to transparency and report findings from safety monitoring publicly, as part of an open and transparent process, to CDC's Advisory Committee on Immunization Practices (ACIP), to FDA's Vaccines and Related Biological Products Advisory Committee, and to update the information for health care providers, caregivers and recipients, as appropriate

QUESTIONS:

Q: HHS agencies have repeatedly told the American people that the vaccines are safe. But CDC's data monitoring system has detected evidence of a link between the vaccines and strokes. Can you acknowledge that your Department's own data show that the vaccines pose risk of serious adverse effects for at least some Americans?

- For decades, our scientific agencies have used safety monitoring systems to look for even the slightest clue of a potential safety issue in our medicines, including vaccines. In most cases, signals detected by these systems do not add up to safety risks, but we investigate all these signals to ensure trust in our medicines.
- As part of CDC's routine surveillance, CDC detected a signal for potential stroke in people ages 65 and older who received the Pfizer-BioNTech bivalent vaccine. In response, CDC and FDA examined several large databases to see if these systems had detected a similar signal. To date, our analyses of all of these large databases do not show an association or increased risk of stroke from the Pfizer-BioNTech bivalent vaccine.
- We continue to conclude that the bivalent vaccines are safe and effective and provide the best protection against COVID-19, and we continue to recommend that Americans of all ages get their updated COVID-19 vaccine right away.

Q: Americans have been pressed to take a series of vaccine doses in less than two years. And now, this Administration is indicating that the public—including children—should

expect a sustained pressure campaign to take a shot each year. If the vaccine is so effective, how come Americans are being asked to take them constantly?

- Evidence continues to show that the COVID-19 vaccine is remarkably safe and effective at preventing severe disease and death.
- Vaccination also does reduce the impact on the US public health and health care system.
- And making sure you are up-to-date on booster shots is an important part of protecting yourself from getting seriously ill or dying from COVID-19.

Program Information

BACKGROUND:

Follow up on Adverse Event Reporting in VAERS

- CDC and FDA co-manage the VAERS system which accepts reports of adverse events after vaccination from healthcare providers, vaccine manufacturers, and the general public.
 - When VAERS reports are received, they are reviewed, processed, and coded.
 - They also undergo a multi-step quality assurance process before being posted publicly to the VAERS website.
- VAERS data are especially useful for quickly detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety concern (or “signal”) with a vaccine.
- VAERS staff from CDC and FDA request follow-up medical records for reports that are classified as “serious.”
 - “Serious” is defined as adverse events resulting in death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, or congenital anomaly/birth defect.

Active Safety Surveillance in the FDA BEST System

- In addition to the VAERS system, FDA and CDC engage in active monitoring of COVID-19 vaccine safety.
- This involves rapidly analyzing information occurring in millions of patient records in large healthcare data systems to verify safety signals identified through passive surveillance, or may be used to detect additional safety signals that may not have been identified elsewhere.
- FDA’s vaccine active surveillance efforts involve the BEST system, which is part of the Sentinel initiative, and comprises large-scale claims data, electronic health records (EHR), and linked claims-EHR databases with a minimum data lag of approximately one month.
- The BEST system covers more than 100 million persons.
- BEST has been used by FDA to identify or evaluate adverse events following COVID-19 vaccination such as anaphylaxis, myocarditis/pericarditis and others. BEST and Medicare data have been used for rapid monitoring of as many as 20 outcomes at a time for each of the COVID-19 vaccine primary series, monovalent and bivalent booster vaccines in the pediatric population, the elderly and people 18-64 years of age.

January 2023 Vaccine Safety Datalink (VSD) Safety Signal

- A safety signal is a statistical finding that the rate of a particular adverse event for a population exceeds an expected rate for that event by a specified threshold—signals do not indicate a safety risk, but rather indicate a need for further analysis.

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- In mid-January, CDC and FDA announced that a preliminary statistical “safety signal,” had been identified prompting additional investigation into a possible safety concern for ischemic stroke in people 65 years and older who received the Pfizer COVID-19 bivalent booster.
- Because transparency and vaccine safety are top priorities at CDC and FDA, together we promptly communicated this signal to the public while we continued to conduct that investigation.
- Analyses by FDA and CMS using Medicare data did not observe a signal for stroke and the Pfizer-BioNTech or the Moderna COVID-19 vaccines in people 65 years and older.
- FDA is further conducting a more robust safety study of the stroke outcome and Pfizer-BioNTech or the Moderna COVID-19 vaccines using Medicare data.
- Extensive review of the latest data revealed that it’s very unlikely that this statistical signal presents a true clinical risk of stroke.
 - **We continue to recommend everyone ages six months and older stay up to date with COVID-19 vaccination.**

Pediatric Vaccine Safety and Adverse Reactions

- Based on the latest vaccine safety data from CDC, mild local and systemic reactions are common among adolescents and younger children and serious adverse events are rarely reported.
- (April 2022) MMWR data from January 2021–January 2022
 - Data from 40 health care systems participating in a large network found that the risk for cardiac complications was significantly higher after COVID-19 than after mRNA COVID-19 vaccination for both males and females in all age groups.
 - 18.1M doses of Pfizer-BioNTech vaccine have been administered to children ages 5–11 years in the U.S.
 - Most VAERS reports (8750/9001, 97%) were non-serious and the most frequently reported adverse events for serious reports were consistent with MIS-C.
 - 20 VAERS reports of myocarditis verified to meet CDC case definition among children ages 5–11 years.

Cybersecurity

TALKING POINTS:

Cyber incidents pose risks to patient data, intellectual property, scientific research, medical manufacturing, and ultimately the ability of health care organizations to safely serve their patients. We must take all steps necessary to prevent them.

Just this month, the Department released a new roadmap to help health care organizations improve their cybersecurity amid new emerging threats and increased attacks on systems. We hope to leverage and further incentivize our private sector partners to strengthen critical infrastructure and safety writ large.

In February, we announced that our Office for Civil Rights is realigning to address this spike in health data breaches. Across the board, we are working to remain nimble internally to respond to bad actors throughout the sector.

In December, the FDA received new authorities through the omnibus requiring medical device manufacturers to implement cybersecurity protections on devices before they hit the market.

QUESTIONS:

Q: How concerned are you about cyber attacks in the healthcare sector? How is HHS helping when cyber incidents occur?

Patient safety is our #1 priority, and safety is compromised by these cyber incidents. A significant consequence of US hospital-directed cyberattacks are the extended disruptions that are caused by long outages and disrupt our healthcare system's ability to provide care (e.g., strain on acute care capacity and ability, causing loss of appointments, loss of services, and delayed medical procedures).

These attacks also cost hospitals financially – one recent attack on a major health system cost them at least \$150M; the \$150 million financial impact includes lost revenues due to business disruption and extra costs to fix the IT issues. These attacks threaten the solvency of health care facilities, and thus can potentially reduce access and availability of care.

When incidents occur, we work with our government partners, such as CISA and FBI to investigate; HHS investigations center around the impact to patient safety.

We stand ready to protect patients when incidents occur through our incident response capabilities within ASPR.

Q: What is HHS doing to support the healthcare and public health sector on cybersecurity?

The best defense is a good offense – we encourage providers to be proactive and take the necessary steps to prevent incidents by securing their networks and data.

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HHS partners with our private sector and interagency partners to release cybersecurity guidance and best practices for health care organizations to implement; we encourage healthcare organizations to remain vigilant.

Additionally, any data breach with patient data is reported to the Office for Civil Rights for further investigation – and follow on action (including penalties) as necessary.

Finally, the FDA plays a big role through the regulation of medical devices – through the FY 2023 omnibus the FDA will now have the authority to require cybersecurity protections on medical devices BEFORE they enter the market.

DEA Regulations

TALKING POINTS (TELEMEDICINE)

- DEA released new **proposed** regulations related to the practice of telemedicine.
- HHS has worked with our DOJ partners on these proposed rules to make sure that people can continue to access telemedicine for critical controlled medications, including buprenorphine treatment for Opioid use disorder.
- Finalizing regulations to extend these flexibilities is critical to ensure minimal disruption and a smooth unwind of the public health emergency
- At HHS, our priority is ensuring access to care for critical services. Pre-pandemic law would be a dramatic rollback of what we learned to be critical access to care that can often be lifesaving.
- We look forward to stakeholder feedback and working with our DOJ colleagues to take that into account and finalize a rule.

TALKING POINTS (X-WAIVER):

- The Omnibus included provisions that better integrate opioid use disorder care into primary care and expand access in rural areas, which the DEA and SAMHSA are implementing. This includes:
 - Removal of the X-waiver and removal of buprenorphine patient caps
 - Implementation of one-time training and education requirements for prescribers wishing to prescribe medication assisted treatment (MAT)
- We are currently working across the Administration to implement these new provisions related to substance use disorders and to produce informative materials for those who are impacted by the new provisions.
- We are supportive of efforts to reduce barriers to treatment because ultimately, this is about saving lives.

QUESTIONS – TELEMEDICINE:

Q: What happens on May 11 when the PHE expires?

- Our work with DEA is about making permanent changes to the regulations that currently apply from pre-pandemic days.
- Once the PHE expires on May 11, and state-level PHE's expire, we know we should not go back to operating the way we did pre-pandemic. We have learned how lifesaving telemedicine is and want to permanently put into place what we know is critical to improving access to healthcare.
- This is why it's critical to take these steps as soon as possible and permanently put in place new, more expansive flexibilities (*as compared to pre-pandemic*) before the PHE expires on May 11.

- We know this is a complicated issue, and we want to make sure we get it right, which is why robust comment is so important during this comment period.

Q: You are encouraging the public to comment but didn't the announcement come out after 7pm on a Friday evening?

- We are in a time limited situation, and we want to get it right. We announced this as soon as we got it cleared because every day counts.
- We need to hear from the public on this rule so we can get this right.
- If these updated, more flexible regulations do not go into place as soon as the PHE expires, we will be left with the older pre-pandemic policies governing telehealth initiation of controlled medications, which were far more restrictive – and everything we learned about improving access to care will be lost.

Q. You claim to support access to buprenorphine, yet the DEA's proposed rules would roll back some flexibilities that have been in place since the pandemic started. Do you support this proposal?

- We have heard lots of differing perspectives on the proposed rules and appreciate the stakeholder engagement.
- We are in a time limited situation, and we want to get this right. Going back to Pre-pandemic rules would dramatically rollback access.

QUESTIONS – X-WAIVER:

Q: How will the removal of the X-Waiver improve access for patients to medications for opioid use disorder?

- The removal of the requirement for practitioners to obtain a waiver will make it easier for qualified practitioners to prescribe medications for opioid use disorder, builds on the Department of Health and Human Services' Overdose Prevention Strategy, and delivers on the call to action in President Biden's Unity Agenda to expand access to evidence-based prevention, treatment, and recovery services.

Q: Isn't removing the training requirement in the X-waiver a concern? Isn't that how we got in this epidemic in the first place?

- The alarming increase in overdose deaths underscores the need for more accessible treatment services, and studies have shown that medication-based treatment promotes long-term recovery from opioid use disorder.
- The spike we've seen in opioid involved deaths during the COVID-19 pandemic requires us to do all we can to make treatment more accessible.
- At the same time, we know that education on substance use disorders is important as practitioners diagnose and treat these conditions. HHS is working with professional societies to ensure that appropriate education is provided to their members so that the

ongoing education and training needs of healthcare professionals are met, regardless of the existence of the X-waiver itself.

Q: Is there abuse potential for buprenorphine-naloxone? In other words, could someone use it to achieve a “high?”

- Though we are aware of some diversion of buprenorphine, these instances are rare and when they do happen, it is typically because people are seeking treatment, not attempting to get "high." This is all the more reason for us to take steps to expand access to buprenorphine.

Q: Will HHS maintain the regulatory flexibilities for medication-assisted treatment for the remainder of the Public Health Emergency while it considers making these policies permanent?

HHS, through SAMHSA, has indicated it will work to revise the relevant regulations to make permanent some flexibilities for opioid treatment programs.

Program Information

FY23 CAA X-Wavier Removal Provision

The FY23 Consolidated Appropriations Act removed the federal requirement for practitioners to apply for a special waiver prior to prescribing buprenorphine for the treatment of opioid use disorder. It also removes other federal requirements associated with the waiver such as discipline restrictions, patient limits, and certification related to provision of counseling which expands the pool of practitioners able to prescribe buprenorphine from 114,000 practitioners to 1.8 million DEA-registered practitioners. FY23 Consolidated Appropriations Act also requires new or renewing Drug Enforcement Administration (DEA) registrants, upon submission of their application, to have at least 8 hours of training on opioid or other substance use disorders for new or renewing practitioners, a board certification in addition medicine or addiction psychiatry from a recognized credentialing body, or have graduated within 5 years from a program that required at least 8 hours of opioid or substance use disorders in their curriculum.

Buprenorphine

Buprenorphine is the first medication to treat opioid use disorder (OUD) that can be prescribed or dispensed in physician offices, significantly increasing access to treatment. As with all medications used in treatment, buprenorphine should be prescribed as part of a comprehensive treatment plan that includes counseling and other services to provide patients with a whole-person approach. Buprenorphine has similar effects to other opioids, such as pain relief, but it does not produce the same degree of effects as full agonists, such as heroin or fentanyl. When taken as prescribed, buprenorphine is safe and effective. It has unique pharmacological properties that help diminish the effects of physical dependency to opioids, such as withdrawal symptoms and cravings, increase safety in cases of overdose and lowers the potential for misuse. As a partial agonist, buprenorphine produces weaker effects than full agonists, which reduces the risk of overdose and misuse. Buprenorphine is an important tool in the treatment of opioid use disorder and can help individuals achieve and maintain long-term recovery.

Background on the Telemedicine NPRM

- This regulation doesn't apply to any scenario in which a person has seen a healthcare professional in person at some point or has seen a healthcare professional in person and been referred to a new healthcare professional for telemedicine visits—so this really is a small subset of prescriptions where an individual has never seen any provider—ever—in person.
- The regulation proposes to allow for a 30 day telemedicine supply and then would require the person to be seen by a physician for a physical exam, although it would not be required that they see the exact prescriber. However, the proposal solicits robust public comment on the 30-day timeframe.
- This regulation would also put no additional registration requirement in place for providers. In the rule, we were able to propose a way that tries to make this as easy as

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possible for providers to continue operating as they are today. This is important to HHS and why we sought comment on this point.

- The proposed rules extend many of the flexibilities adopted during the public health emergency, but would no longer, as proposed, allow for patient-initiated treatment via telemedicine for stimulants or opioids. For these substances, once a patient has seen a doctor or been referred by a doctor, telemedicine visits can commence.
- A driving concern in the development of these rules was ensuring that patients can continue to have access to care.
- Another central concern was continuing to ensure that patients can access medication for opioid use disorder. Foundational concern: everyone who needs MOUD should be able to have safe and ready access. We continue to work with DEA internally to get the rules further on this point.
- The proposed rule's new guardrails would take effect six months from when the PHE ends.

Debt Ceiling

TALKING POINTS:

- The Administration's position has been clear – we must avoid dangerous brinksmanship and agree to a clean raise of the debt ceiling.
- The President's budget will build on the last few years' progress, invest in America, and strengthen our fiscal outlook.
- The Administration welcomes a conversation with congressional Republicans about their competing vision, and that's why we've urged them to put forward their own budget, which is a necessary step to having that conversation.
- The President has been clear about some things he won't agree to, including cutting Medicare benefits or taking away people's health care.

QUESTIONS:

Q: Will this Administration accept work requirements for Medicaid beneficiaries?

- Let's be clear: Medicaid is a lifeline to tens of millions of hardworking American families across the country.
- My goal is to use all available tools to protect and strengthen the Medicaid program, making it easier, not harder for people to get and keep health insurance that helps them to become healthy, not pulls the rug out from under them.
- *If pushed:*
We would not approve any demonstration that would result in significant numbers of Medicaid beneficiaries losing coverage.

Q: Will this Administration negotiate on Medicaid

- Medicaid is a lifeline to tens of millions of hardworking American Families- including one in every two children. The President's budget would strengthen our fiscal outlook and cut the deficit by investing in America, not paying for it on the backs of hardworking families.

Q: What will cuts to non-defense discretionary spending mean for HHS?

- This is the funding for medical research, public health programs at the CDC and other HHS agencies, grants for substance use and mental health treatment, and various other programs.
- Cuts will have a significant impact on the Department's work and ability to provide services, assist people in need, and make necessary investments.

(CMS) Drug Pricing Reform

TALKING POINTS:

- The Budget builds on the transformative prescription drug provisions included in the Inflation Reduction Act to further lower the cost of prescription drugs for Americans:
 - Strengthen Medicare’s newly established drug pricing negotiation power by allowing Medicare to negotiate prices for more drugs and bringing drugs into negotiation sooner after they launch, saving \$160 billion over 10 years.
 - Extend the requirement that drug companies pay rebates when they increase prices faster than inflation to commercial health insurance, not just Medicare.
 - Limit cost-sharing for insulin to \$35 per month for all consumers covered by commercial plans, not just Medicare beneficiaries.
- The Budget further reduces out-of-pocket costs for people with Medicare by capping copayments for Part D generic drugs at maximum of \$2 per prescription per month.
- The Budget addresses the high cost of drugs in Medicaid and CHIP by establishing a process for CMS to lead states in negotiating supplemental rebates to pool purchasing power for lower prices.

QUESTIONS:

Q: How many drugs are you including in your proposal to expand drug price negotiation to achieve \$160 billion in savings over 10 years? Is that realistic?

A: First, let me say that I am proud to be part of the Administration that passed one of the most significant health reform bills since the creation of Medicare. The Inflation Reduction Act makes Medicare stronger for current and future enrollees. It makes health care more accessible, equitable, and affordable by lowering what Medicare spends for prescription drugs and limiting increases in prices, reducing the deficit by \$159 billion.

Our Budget builds on the Inflation Reduction Act by increasing the number of drugs subject to negotiation, eventually negotiating on up to 40 drugs, and making drugs eligible for negotiation sooner after their launch. Expanding the Drug Price Negotiation Program will lower costs for people with Medicare and the program, for an additional \$160 billion in savings over 10 years.

We will take the increased savings and put them directly into the Medicare trust fund, helping to extend Medicare’s solvency. As always, we will continue to work with Congress on the specifics of these proposals.

Q: Won’t drug price negotiation raise the prices of new drugs, so doesn’t the Budget contribute to higher prices for new drugs?

A: Manufacturers use many factors when considering their launch prices and will continue to price their drugs at the price they believe the market will bear. We are proposing to make drugs eligible for negotiation sooner after they launch, permitting time on the market for five years. Under current law and under our proposal, any drug or biological product selected for negotiation will have been on the market for some time. CBO didn’t estimate that the new Drug

Price Negotiation program would have a significant impact on launch prices, and we do not believe our proposal will contribute to significantly higher launch prices.

Q: Aren't drug price negotiations really price controls that will hinder drug development?

A: We support innovation and believe it is vitally important that people with Medicare have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.

By reducing prices for high-cost drugs, our expansion of Medicare drug price negotiation will not only save money for the federal government, but it will also cut Medicare beneficiary out-of-pocket costs by billions of dollars.

Q: Won't drug price negotiation crush innovation and kill hundreds of new cures? Studies have found that the IRA's negotiation provision would kill up to 342 cures.*

A: We support innovation and believe it is vitally important that people with Medicare have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.

Medicare's drug price negotiation program will make drugs more affordable for people with Medicare. Remember, only drugs that have been approved or licensed by the FDA for a number of years are eligible for negotiation.

*[The number 342 has been used by some to argue that drug price negotiation will lead to fewer new drugs and refers to a [University of Chicago study](#) based on provisions in H.R.3, Lower Drug Costs Now, that finds fewer drug approvals ranging from 167 to 342.]

Q: Regarding making the Medicaid Drug Rebate Program (MDRP) optional for territories, why is this needed? Doesn't joining the MDRP result in more savings for territories?

A: Territories' Medicaid programs operate under a unique set of conditions that differ from states. While participating in the Medicaid Drug Rebate Program leads to savings, these savings could be more than offset by the increase in costs from the additional drugs that territories would need to cover under the MDRP. The five territories are very different and will not experience the same economic impact by joining as states. This proposal effectively gives territories the option to make the best choice for their Medicaid program resources and needs. Excluding sales of drugs to territories from the average manufacturer price and best price calculations mitigates possible increased drug prices in territories.

Program Information

Medicare:

- The Budget includes Medicare drug pricing proposals that save \$158.7 billion over 10 years.
 - Expands Medicare prescription drug price negotiation by allowing Medicare to negotiate prices for more drugs (20 in 2026; and 40 every year thereafter) and bringing drugs into negotiation sooner after they launch (permitting time on the market for five years for all drugs). Saves \$160 billion over 10 years.
 - Limits Medicare Part D cost-sharing on high-value generic drugs to \$2 per prescription per month. Costs \$1.3 billion over 10 years.

Medicaid:

- The Budget includes proposals in Medicaid and CHIP that save \$7.6 billion over 10 years.
 - Establishes a process under which CMS and partnering state Medicaid programs partner with a private sector contractor to negotiate supplemental rebates from drug manufacturers. Saves \$5.3 billion over 10 years.
 - Applies Medicaid Drug Rebates to Separate CHIP to align drug rebate policies for separate CHIPs with those in Medicaid and Medicaid expansion CHIPs. Saves \$2.3 billion over 10 years.
- The Budget includes the following technical proposal:
 - Modifies the Medicaid Drug Rebate Program (MDRP) to provide territories the option to participate in the MDRP, and addresses concerns of drug manufacturers increasing prices for territories by removing territory prices from certain MDRP calculations. These two policies provide territories the flexibility they need to make a decision specific to their unique situations.

Private Insurance:

- The budget strengthens the affordability of prescription drugs for consumers by providing \$20 million in HHS funding (\$1.36 billion government-wide) to cap cost-sharing for insulin at \$35 per month. The budget also expands drug inflation rebates in Medicare to include the costs of drugs in the commercial market when making rebate calculations.

BACKGROUND:

Expansion of Medicare Prescription Drug Price Negotiation

- This proposal builds on Section 11001 of the Inflation Reduction Act by expanding the number of drugs negotiated starting in FY 2026.
- Current law requires that Medicare negotiate 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest

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total Medicare Part B spending. The number of drugs with negotiated prices available will accumulate over time.

- OMB used the following specifications to derive the \$160 billion savings estimate from expanding the Medicare Drug Negotiation Program.
 - Require Medicare to negotiate 20 Part D drugs in 2026 and 40 Part B and Part D drugs each subsequent year. The below table illustrates the change in count of eligible drugs.

	2026	2027	2028	2029	2030	2031	2032	2033	2024-2033
Current Law Total Drugs	10	15	15	20	20	20	20	20	140
Proposed Law Total Drugs	20	40	40	40	40	40	40	40	300

- Decrease the number of years of exclusion from negotiation from 7 years to 5 years for small-molecule/new chemical entity drug products and 11 years to 5 years for biological products.
- Decrease the maximum fair price calculation by lowering the defined percentage by 5 percent for each product type. See table below for applicable percentages. There are no changes to the price benchmarks.

Ceiling Price (Lowest of the below benchmarks)	X	Defined percentage (Whichever of the below qualify)
The average of non-FAMP for 2021 inflated by CPI-U to the year prior to the selection year		Long-monopoly drugs: 35% for drugs which have been approved for at least 16 years
Starting with the second year of the negotiation program and subsequent years, the average non-FAMP for the year prior to selection		Extended-monopoly drugs: 60% for drugs which have been approved for 12 through 16 years
For Part B drugs: the lesser of the drug's Average Sales Price (ASP) or wholesale acquisition cost (WAC)		Short-monopoly drugs and vaccines: 70% for drugs and vaccines approved less than 12 years

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For Part D drugs: an enrollment-weighted average of the plan specific net negotiated price amounts for each PDP and MA-PD plan for the most recent year for which the data are available

Extended- and long-monopoly vaccines:
70% for vaccines approved 12+ years

Drug Pricing Executive Order

TALKING POINTS:

- HHS was tasked by the President to select models to test to bring down prescription drug costs.
- I selected three models identified by the Innovation Center that we believe will lower prescription drug costs and improve access for people with Medicare and Medicaid, including, in Medicare, access to certain generic drugs for no more than \$2.
- To help identify model options, we solicited input from a variety of sources including beneficiary advocates, health care providers, and prescription drug manufacturers, and we look forward to additional input as these models are further developed.

If pressed about mandatory models

- Two of the models are voluntary. Only one model, the Accelerating Clinical Evidence Model, would be mandatory for physicians billing Medicare for Part B drugs, and this model would only be implemented after a full notice and comment rulemaking cycle.

QUESTIONS:

Q: The FDA's Accelerated Approval Program has brought groundbreaking therapies to patients years before these products would have otherwise reached the market. The Accelerating Clinical Evidence Model recently announced by CMS risks undermining this progress. Will you consider canceling or delaying the Model?

- The Accelerating Clinical Evidence Model will not change the way CMS covers new drugs, and it does not change the FDA accelerated approval process. The model is intended to test whether changes to Medicare payment might encourage evidence development via timely completion of confirmatory trials. We are still exploring the specific approaches to payment adjustments, and we look forward to close consultation with the FDA and hearing from stakeholders on how the Model should be developed.

Q: The IRA did not address the high cost of drug launch prices; how will these models tackle that challenge?

- High launch prices are among many factors that impact affordability for beneficiaries. Each of the selected models addresses the objectives of the President's executive order and meets the selection criteria of increasing affordability, accessibility, and feasibility of implementation.

Q: The IRA did not address the perverse incentives created by PBM rebates, how will these models tackle that challenge?

- The executive order directed the Innovation Center to explore a variety of factors addressing prescription drug costs. The effect of rebates on prescription drug costs is one among many factors that contribute to high and rising drug costs for beneficiaries. The selected models address the objectives of the President's executive order and meet the selection criteria of increasing affordability, accessibility, and feasibility of implementation.

Q: Part D plans already offer low-cost generics; what does the High-Value Drug List model intend to accomplish?

- This model would encourage plans to expand their current low copay drug offerings and provide beneficiaries access to a standardized list of generics with copays of no more than \$2 across participating plans. The simplicity and consistency of the drug list could provide beneficiaries with greater predictability and transparency with their drug costs and enable them to more easily access low-cost generics.

Q: How does the Medicaid Cell & Gene Therapy Access Model differ from what states can already do?

- State Medicaid agencies may negotiate with manufacturers for supplemental rebates on prescription drugs and may form multi-state purchasing pools for purposes of these negotiations. However, states' abilities vary, and the resources necessary to negotiate outcomes-based supplemental rebate agreements are far greater than other types of rebate agreements. This model will help to address that challenge for states and encourage adoption of outcomes-based agreements on a broader scale for certain cell and gene therapies, like for sickle cell disease and cancer.

Early Childhood Education

(Dollars in Millions)

Discretionary Table	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Child Care and Development Block Grant (Discretionary)	8,021	9,000	+979
Head Start (Discretionary)	11,997	13,112	+1,115
Preschool Development Grants (Discretionary)	315	360	+45
Total, Discretionary	20,333	22,472	+2,139

Mandatory Table	FY 2023 Enacted	FY 2024		10 Years
		Budget	+/- FY 2023 Enacted	
Budget Authority - Child Care Entitlement	3,550	3,550	-	35,500
Total, Child Care Entitlement	3,550	3,550	-	35,500
Budget Authority - Affordable Child Care for American Families	-	9,900	-	400,000
Budget Authority - Universal Preschool	-	5,000	-	200,000
Total, Early Care and Education	-	14,900	-	600,000

Talking Points:

- Approximately 1.5 million children receive child care assistance from the Child Care and Development Fund. The new mandatory investment in high-quality child care would expand coverage options to more than 16 million children in low- and middle-income families.
- Under our budget, lowest income families would pay nothing and middle-income families would pay no more than \$10 per day per child for child care.
- The budget would allow all four million 4-year-old children in the nation to have access to high-quality, universal, free preschool, while also charting a path to expand free preschool to 3-year-olds. Currently, less than half of all 4-year-old children and just 17 percent of all 3-year-old children attend publicly funded preschool.
- The budget provides \$22.5 billion in discretionary Child Care, Head Start, and Preschool Development Grants, an increase of \$2.1 billion over FY 2023 Enacted. The budget also

continues to help over 2.5 million children have access to early learning programs through our existing Child Care, Head Start, and Preschool Development Grants programs.

QUESTIONS:

Q: How will Early Childhood Education help low and middle-income families access high quality and affordable child care?

- The President’s Budget includes \$600 billion over 10 years to expand access to affordable, high-quality child care and free, high-quality preschool, helping children learn, giving families support, and growing the economy.
- Low- and middle-income families will pay the lowest co-pays – with a goal of ensuring that the lowest income families pay nothing and that most families pay no more than \$10 per day per child.
- A median-income family with young children saves about \$400 per month while accessing higher quality care.

Q: What is in the Early Childhood Education - Affordable Child Care for American Families proposal?

- The FY 2024 Affordable Child Care for American Families proposal costs \$400 billion over 10 years and provides higher federal matching funds for child care providers serving low- and middle-income families and allows those families to pay the lowest co-pays, with a goal of ensuring that the lowest income families pay nothing and that most families pay no more than \$10 per day per child.

Q: What is in the Early Childhood Education - Universal Preschool proposal?

- The Universal Preschool proposal expands high-quality preschool to approximately four million 4-year-old children, with states later expanding to 3-year-old children once preschool is expanded to all 4-year-old children.
- The Universal Preschool proposal includes funding to provide access to preschool to children in underserved communities in states that do not choose to participate in the new preschool program, so that families in every state have access to high-quality preschool.

Program Information

- **Mandatory ACF Early Care and Education:** +\$600 billion over 10 years to make more than 16 million children eligible for affordable, high-quality **child care**, and to provide universal preschool to approximately four million 4-year old children.
 - The HHS Secretary administers the program in collaboration with the Secretary of Education.
 - Child Care Entitlement: \$3.55 billion in FY 2024 to help families with low incomes afford child care and improves the quality of child care for all children. This is permanently authorized every fiscal year.
 - Child Care Entitlement and Child Care Development Block Grant together make up the Child Care and Development Fund.
- **Discretionary Programs:** The budget invests in early education with increases to the Child Care and Development Block Grant, Head Start, and Preschool Development of \$2.1 billion including:
 - Child Care Development Block Grant: +\$979 million above FY 2023, for a total of \$9.0 billion to support low-income, working families by providing access to affordable, high quality early care and afterschool programs. This investment will serve approximately 2 million children.
 - Head Start: +\$1.1 billion above FY 2023, for a total of \$13.1 billion to promote school readiness, development, health, and family well-being of children ages birth to 5 from low-income families.
 - Preschool Development Grants: +\$45 million above FY 2023, for a total of \$360 million to build state and local capacity to provide preschool to 4-year-olds from low- and moderate-income families.

Background:

HHS Early Childhood Education and Child Care Serve Nearly 2.5 Million Children

ACF investments in child care, preschool, and Head Start support our next generation. In 2020, the Child Care and Development Fund served 1.5 million children and Head Start served nearly 1 million children.

Child Care, Preschool, and Head Start Funds Provide Wide-Ranging Support

- ACF investments in child care, preschool, and Head Start support children and families through a wide range of activities.
- Child Care and Development Funds support activities to improve the quality of child care for all children, and funds are earmarked for improving the quality and supply of child care for infants and toddlers.
- ACF uses the Child Care and Development Fund collaboratively with the Head Start Program, to identify innovations in child care administration and to bring best practices to teachers and caregivers across early childhood settings.

Equity

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
ACF	71,470	94,374	+22,904
ACL	2,105	2,551	+445
AHRQ	4	12	+9
CDC	378	674	+297
FDA ¹	19	19	--
HRSA	7,589	8,634	+1,045
IHS ²	7,105	9,650	+2,545
NIH	95	95	--
CMS	83	82	-1
OASH	75	86	+11
OCR	40	78	+38
Total Program Level	88,963	116,256	26,293

1/The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year.

2/ Reflects total IHS funding with the exclusion of third-party collections. The FY 2024 budget proposes mandatory funding for Contract Support Costs and Section 105(l) Leases. Funding for these activities is discretionary in FY 2023.

TALKING POINTS:

- Equity remains a core value and consideration in the Department's budget and program implementation. We strive to reduce systemic health and social disparities for individuals and families, and combat inequities in access to care.
- Some highlights in our budget – we included \$8.6 billion to care for low-income and underserved populations through Health Centers, health care workforce expansion, rural health, HIV/AIDS, and maternal and child health services. The budget takes long-overdue action to improve the health status of over 2.8 million American Indians and Alaska Natives served by the Indian Health Service (IHS) with historic funding levels. ACF also will provide \$50 million in new grants to address racial inequities in child welfare, and reduce overrepresentation of racial / ethnic minority children and families.
- The budget invests over \$2.6 billion to provide critical services and supports to older adults and people with disabilities, with a particular emphasis on serving the most vulnerable in greatest social and economic need (through Administration for Community Living (ACL) programs).

QUESTIONS:

Q: In what ways has CMS focused on equity in the budget?

There are many proposals in the budget that have a positive equity impact. Key examples include:

- **Medicaid:** The budget eliminates barriers to Pre-exposure Prophylaxis (PrEP) for HIV/AIDS, increases access for Medicaid beneficiaries seeking HIV prevention tools, including populations most vulnerable to HIV/AIDS. The budget also requires postpartum coverage for 12 months under Medicaid, including for populations with the highest maternal and infant mortality rates. It also supports dually-eligible individuals by reducing administrative barriers for enrollment and simplifying the process for renewing eligibility in the Medicare Savings Program.
- **Medicare:** The budget also improves data on health disparities by requiring post-acute care providers to report standardized data on social determinants of health, and allows the collection of demographic and social determinants data through Medicare quality reporting programs. The budget adds Medicare coverage of services furnished by community health workers to improve access for underserved beneficiaries
- **Private Insurance:** The budget would fulfill the intention of the ACA by providing a premium-free plan to individuals below 138 percent of the poverty level in states that have not expanded Medicaid, potentially decreasing the number of uninsured individuals by over 2 million. This proposal is a \$200 billion allowance government-wide.
- **Program Management:** The budget includes \$25 million in discretionary budget authority for an initiative to develop tools for States and tribes to address disparities, expand innovative approaches for integrating equity into CMS's programs and policies, build analytic systems to integrate data on underserved populations, and develop dashboards and other products to support interventions to reduce disparities.

Q: The CDC declared racism a public health emergency in 2021. What is the Department doing to improve minority health and reduce health disparities?

- The Health Resources and Services Administration improves health outcomes and achieves health equity through access to quality services, a skilled health workforce, and innovative, high-value programs. HRSA is the primary federal agency that improves access to healthcare services for people who live in underserved and rural communities across the country.
- The National Institute on Minority Health and Health Disparities will continue to expand investments in research on health disparities, fostering collaborations and partnerships to address long-standing inequities.
- NIH will continue to support the UNITE initiative, an NIH-wide effort committed to ending racial inequities across biomedical research.
- Congress provided increased funding for disparities research at NIMHD in FY23. This budget will continue to fund these efforts.

Program Information

- **ACF:** +\$22.9 billion above FY 2023, for a total of \$94.38 billion to foster health and well-being by providing federal leadership, partnership, and resources for the compassionate and effective delivery of human services.
- **ACL:** +\$445 million above FY 2023, for a total of \$2.6 billion to support ACL programs, which target those in greatest social and economic need, with particular attention on people with disabilities and older adults who are also further marginalized due to race, ethnicity, sexual orientation, gender identity, poverty, language spoken, or other factors, and/or are at risk of institutionalization.
- **AHRQ:** +\$9 million above FY 2023 to support grant supplements focused on advancing diversity within the health services research community and data activities aimed at improving maternal healthcare. AHRQ's investments in equity also support research grants focused on making care more equitable.
- **CDC:** +\$297 million above FY 2023, for a total of \$675 million to support a range of CDC programs specifically focused on addressing health disparities and promoting health and wellbeing of vulnerable or underserved populations. This includes priority investments in programs to address social determinants of health, cancer disparities, childhood lead poisoning prevention, and health impacts of climate change.
- **CMS:** Includes a total of \$82 million of discretionary funding to identify and address health disparities by expanding outreach and education to underserved populations about how to access health care coverage, collect and analyze data on disparities, and engage with stakeholders to engage with stakeholders about rural health needs.
- **FDA:** Includes a total of \$19 million to advance meaningful inclusion of minority populations in clinical trials to address health disparities as well as expanding research and outreach effort to underserved and vulnerable communities on nutritional and toxicology programs.
- **HRSA:** +\$1 billion above FY 2023, for a total of \$8.6 billion for various programs to advance health equity by providing access to care for underserved, low-income at-risk groups through Health Centers, health care workforce expansion, rural health, HIV/AIDS, maternal mortality and morbidity, and child health services. Approximately 90% of health center patients are individuals or families living at or below 200% of the Federal Poverty Guidelines and approximately 63% of health center patients are racial/ethnic minorities. HRSA expects to sustain health centers' provision of affordable, accessible, quality, and cost-efficient care to 33.5 million patients. HRSA will continue its contribution to reducing AIDS-related mortality for low-income and uninsured people living with HIV/AIDS by ensuring the provision of HIV medications and related services to 289,000 persons in FY 2024 through the AIDS Drug Assistance Program.
- **NIH:** The FY 2024 budget will continue to enhance health disparities and inequities research at \$95 million. NIH will continue to support the UNITE initiative, an NIH-wide effort committed to ending racial inequities across the biomedical research enterprise that was launched in early FY 2021 and continue funding health disparities research across multiple Institutes and Centers.
- **IHS:** +\$2.5 billion above FY 2023, for a total of \$9.7 billion for IHS in FY 2024. The budget builds on the historic enactment of advance appropriations by providing \$8.1

billion in discretionary funding for Services and Facilities to support 2.6 million additional hospital and clinic visits, 529 thousand additional dental services, and 146 thousand additional mental health visits in 2024. The budget also includes \$1.6 billion in proposed mandatory funding for Contract Support Costs, Payments for Tribal Leases, and the Special Diabetes Program for Indians. The Administration continues to support full mandatory funding as the most appropriate long-term funding solution for IHS. To this end, the budget would reclassify Contract Support Costs and Section 105(l) Leases to mandatory in FY 2024 and would make all IHS funding mandatory beginning in FY 2025. Funding for IHS would grow by 382 percent over 10-years under this approach.

- **OASH:** +\$11 million above FY 2023, for a total of \$86 million for the Office of Minority Health to lead, coordinate, and collaborate on minority health activities across the Department, including leadership in coordinating policies, programs, and resources to reduce health care disparities and advance health equity in America. In FY 2024, investments will focus on areas with high rates of adverse maternal health outcomes or with significant racial or ethnic disparities in maternal health outcomes.
- **OCR:** +\$38 million above FY 2023, for a total of \$78 million to support the expansion of enforcement and related policy work to support the Administration's equity priorities, including non-discrimination on the basis race, color, national origin, and sex.

BACKGROUND:

- **Equity Funding:**
This paper only covers select activities, targeted programs and funding directly related to the Administration's priority to advance equity across all programs, as identified by OpDivs and StaffDivs.
- **Executive Order:**
The budget builds on the President's Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and supports targeted initiatives across HHS aimed at tackling health disparities, which disproportionately impact low-income individuals, racial and ethnic minorities, and other underserved populations, including individuals living with HIV/AIDS, tribal communities, older Americans, people with disabilities, women, and children.

Fentanyl/Overdose Prevention

TALKING POINTS:

- Drug overdoses are a leading cause of death for Americans - more than 107,000 Americans died from a drug overdose in the 12-month period ending in August 2022.
- The overdose crisis has evolved beyond the use of prescription opioids to include increased use of illicit opioids, such as fentanyl, and in combination with other drugs like cocaine and methamphetamine. We are focused on using evidence-based strategies to save lives like using naloxone and expanding access to medications to treat opioid use disorder.
- The budget addresses the **overdose epidemic** by investing \$10.9 billion, including \$9.8 billion in discretionary funding, in programs addressing opioids and overdose-related activities across HHS. These programs support the goals of the HHS Overdose Prevention Strategy.

If pressed for specific examples:

- \$6.2 billion for SAMHSA programs, including the Substance Use Block Grant and the State Opioid Response Grant, which provide grants to states to address the overdose crisis.
- \$736 million for the CDC to expand overdose prevention programs.
- \$79 million for the FDA to implement the Overdose Prevention Framework, which supports programs to promote appropriate prescribing, expand access to naloxone, ensure access to evidence-based treatments, and increase surveillance, enforcement, and indictment of illegal products at international mail facilities.
- \$50 million for a new Community Harm Reduction and Engagement Initiative that will support distribution of naloxone, prevent overdose deaths, increase testing for HIV and viral hepatitis, and provide peer support services. This program will provide much needed services to 330,000 people.
- \$78 million for First Responder Training program and \$28 million for grants to prevent prescription drug and opioid overdose—increases for these SAMHSA programs will directly increase access to naloxone and prevent overdose deaths.
- \$28 million for Building Communities of Recovery, an increase of \$12 million, to expand peer recovery services, expanding access to shared life experiences and community knowledge from peers to program participants.

QUESTIONS:

Q: Do you think that we should schedule fentanyl and fentanyl analogues?

- It is a priority for this Administration to schedule the class of fentanyl-related substances. At the same time, we should make it easier to research Schedule I substances, and create an off-ramp to de-schedule or lower the schedule of a fentanyl-related substance if data

show it doesn't belong in Schedule I. These actions are all included in the Biden Administration's interagency agreement, which I support.

- We do know that the introduction of synthetic opioids like illicitly manufactured fentanyl has led to significant increases in overdose deaths. Of significant concern is the increasing contamination of the drug supply with fentanyl. This is leading to many individuals becoming exposed to fentanyl without even knowing or expecting it.
- Given the escalating overdose crisis and the negative impact of the COVID-19 pandemic, HHS experts came together to create a comprehensive Overdose Prevention Strategy meant to strengthen our primary prevention efforts and increase access to the full continuum of care and services for individuals with substance use disorder and their families.
- The availability of fentanyl underscores the need to expand access to quality prevention, treatment, recovery support, and harm reduction services. Ultimately, this is about saving lives.

Q: Can you talk about the importance of education on fentanyl contamination in the cases of drug overdose deaths?

- We know that the introduction of synthetic opioids like illicitly manufactured fentanyl have led to significant increases in overdose deaths. We also know that people are increasingly becoming exposed to fentanyl that has made its way into the drug supply.
- SAMHSA's First Responders-Comprehensive Addiction and Recovery Act Grants is one example of a program that works to train and provide resources to first responders and other key community members, distribute naloxone and fentanyl strips, and seek to reverse overdose deaths associated with fentanyl.
- We are proposing a \$22 million increase for this critical program.
- Other grants such as the State Opioid Response program and Comprehensive Opioid Recovery Centers (CORC) grant also support access to education, outreach, and the continuum of services people with opioid and/or stimulant use disorders need.

Program Information

- Given the escalating overdose crisis and the negative impact of the COVID-19 pandemic, in October 2021, HHS experts came together to create and release a comprehensive Overdose Prevention Strategy meant to strengthen our primary prevention efforts and increase access to the full continuum of care and services for individuals with substance use disorder and their families.
- The Overdose Prevention Strategy aims to combat opioid overdoses by applying best-available data and evidence to maximize health equity, inform SUD-related policy and actions, integrate SUD into other types of health care and social services, and reduce stigma. The Strategy includes elements from the full continuum of care including prevention, harm reduction, expanding quality treatment and sustaining recovery
- The FY23 Omnibus included provisions that better integrate opioid use disorder care into primary care and expand access to overdose prevention in rural areas, which DEA/SAMHSA are working to implement:
 - Removal of the X waiver, removal of buprenorphine patient caps, and implementation of one-time training and education requirements for prescribers wishing to prescribe MAT. Each of these provisions increase access to treatment.
 - SAMHSA's SABG, SOR, Building Communities of Recovery and Medication Assisted Treatment for Prescription Drug/Opioid Addiction grant programs received increases in the FY 23 Omnibus and are key components of the Overdose Prevention Strategy.

Food Safety

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA	1,520	1,730	+210

Talking Points:

- Today, we are in the midst of a **food revolution**—including how foods are produced, delivered, and handled.
- The budget proposes **\$1.7 billion** to invest in resources, staff, and technology that address rapid changes in human and animal food safety systems and human nutrition.
- Key investments include **protecting** in infant and toddler foods, **enhancing nutrition and food labeling**, and improving the security of the food **supply chain. For future disruptions.**

QUESTIONS:

Q: How will FDA’s organizational changes improve its ability to carry out its food safety responsibilities?

- FDA is implementing a new, transformative vision for the FDA Human Foods Program, which will focus on protecting and promoting a safe, nutritious U.S. food supply that more quickly adapts to an ever-changing and evolving environment.
- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Q: Does the FY24 budget’s proposed increases for Foods fund these organizational changes?

The proposed increases cover needs identified in the Foods program even before the organizational changes began. As we continue to implement our transformative vision for the Human Foods Program and identify additional needs, we will come back to Congress.

Q: How will FDA’s organizational changes improve its ability to carry out its food safety responsibilities?

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- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Gun Violence and Community Violence

TALKING POINTS:

- Firearm injury is among the 5 leading causes of death for people aged 1–44 in the United States.
- Addressing the gaps in knowledge and identifying effective prevention strategies are needed to keep individuals, families, schools, and communities safe from firearm injury and death.
- Community violence directly or indirectly affects everyone in a community as people grieve for friends and neighbors and avoid engaging in neighborhood activities. In addition, violence creates strain on education, justice, and medical systems and weakens local business growth and prosperity, limiting community resources and preventing the achievement of other community goals.

QUESTIONS:

Q: Gun violence in the U.S. is at an all-time high, it is clearly a public health threat. Will you declare a PHE for gun violence?

- You're correct, this is a crisis—firearm injury is among the 5 leading causes of death for people aged 1–44 in the United States.
- The most important thing we can do is to continue to support prevention, education and research efforts across this country.
- We want to keep all options on the table, but we are not declaring a PHE at this time.

Program Information

Firearm Injury and Mortality Prevention Research

- The Budget will continue to invest in this research. Additional funding will be used to:
 - Expand and improve firearm research projects
 - Develop innovative and promising prevention interventions
 - Rigorously evaluate the effectiveness of current strategies to keep individuals, families, schools, and communities safe from firearm-related injuries, deaths, and crime
 - Improve collection and dissemination of timely data
- *Community and Youth Violence Prevention*
 - The Budget also proposes a significant investment to expand the reach of CDC's community violence work to help stem the rise in violence in cities across the country. CDC will focus on youth perpetration and victimization.

Harm Reduction

TALKING POINTS:

- HHS is fully committed to harm reduction as part of our comprehensive approach to address addiction and the overdose epidemic.
- More than 107,000 Americans died from a drug overdose in the 12-month period ending in August 2022. We must do everything we can to save lives.
- The Administration has a comprehensive overdose prevention strategy of primary prevention, harm reduction, treatment, and recovery support services.

QUESTIONS:

Q: Can HHS or SAMHSA grantees use any federal dollars to purchase and distribute needles?

The FY 2023 Consolidated Appropriations Act Congress carried previous appropriations language that allowed for the purchase and distribution of needles so long as both local public health or local law enforcement deem it appropriate, or the State or local health department in concert with CDC has determined that the State or local jurisdiction is not experiencing or at risk for a significant increase in hepatitis infections or a HIV outbreak due to injection use.

Q: But I thought that the FY23 Omnibus included provisions that prevented grantees/states from using federal funds for the purchasing or distribution of drug paraphernalia?

- The Administration is focused on a comprehensive strategy, including prioritizing the use of evidence-based harm reduction strategies like providing naloxone and fentanyl test strips, **and what is allowed under federal, state, and local law.**
- SAMHSA is fully committed to harm reduction as part of its comprehensive approach to address addiction and the overdose epidemic. Our approach also includes expanding access to evidence-based prevention, treatment, recovery supports services.

Q: Is SAMHSA or HHS funding going to crack pipes in safe smoking kits? What else is in a safe smoking kit? When is it ever safe to smoke crack or meth?

- To answer your question directly, no federal funding will be used directly or through subsequent reimbursement of grantees to put pipes in safe smoking kits.
- The Administration is focused on a comprehensive strategy, including prioritizing the use of evidence-based harm reduction strategies like providing naloxone and fentanyl test strips, and what is allowed under federal, state, and local law.
- HHS is fully committed to harm reduction as part of its comprehensive approach to address addiction and the overdose epidemic. Our approach also includes expanding access to evidence-based prevention, treatment, recovery supports services.

Program Information

- The 2020 National Survey on Drug Use and Health estimated that approximately 37.5 million people, or about 13.5 percent of all Americans aged 12 and older, would benefit from community harm reduction services. The budget proposes to provide \$50 million for a harm reduction program to continue the initiative first created in the American Rescue Plan. Reaching approximately 330,000 individuals, the program would support distribution of naloxone, prevent overdose deaths, increase testing for HIV and viral hepatitis, and provide peer support services.
- The budget also proposes to increase access to naloxone by providing \$78 million to the SAMHSA First Responder Training program, an increase of \$22 million over FY 2023 enacted, and providing \$28 million for grants to prevent overdose, an increase of \$12 million above FY 2023 enacted.
- We are growing investments in crisis response and harm reduction and value the importance of expanding our behavioral health workforce to ensure we are reaching underserved populations.

Head Start -- Protecting Safety and Safeguarding Funds (Fraud)

TALKING POINTS:

- Protecting the health and safety of children and safeguarding federal funds are central to the Administration for Children and Families' (ACF) mission across programs.
 - HHS places the utmost priority on child health and safety; while rare, any incidents that jeopardize child safety are unacceptable.
 - HHS also takes seriously allegations of fraud, misuse and theft of federal funds.
- ACF issued guidance to Head Start programs on the requirements for reporting child incidents and provided training and technical assistance to Head Start programs on recognizing symptoms of abuse and neglect, using active supervision to create a safe environment for children, and understanding the responsibilities of a mandated reporter.
 - Recently, the Agency moved swiftly to suspend federal financial assistance in two cases based on the serious allegations of fraud, misuse and theft of federal funds.
- ACF is working diligently to implement the recommendations of the OIG in its report, *Child Safety in Head Start Programs*, and will continue to advance its rigorous national standards and reporting requirements.
 - We will continue to work with our programs to make any necessary improvements so that every child has the opportunity to thrive and reach their full potential in a safe and healthy environment. OHS will also continue to prioritize safeguarding federal funds, take all allegations about the misuse of federal funds seriously, and ensure any complaints are investigated and referred to the proper authorities if fraud is suspected.

QUESTIONS:

Q: Why did it take HHS three weeks to issue an emergency suspension in the New York case?

- The indictments did not include any allegations regarding children's safety or well-being.

Q: How many children may be impacted by the emergency suspension of these Early Head Start and Head Start programs?

- HHS is committed to minimizing the disruption to children and families impacted by this grant suspension. These grantees claimed to serve a combined total of approximately 740 children.

Q: What resources were available to assist impacted children and families?

- HHS set up a website and call hotline to assist families in finding a new early childhood program to meet their needs.

Q: What action has HHS taken to safeguard these grant funds following the indictment prior to issuing the emergency suspensions?

- On January 11, 2023, upon notification of the arrests and public release of the indictment, HHS implemented a funding lockdown on the Head Start grants for Project Social Care Head Start and NYC Early Learning Company.

Q: Does HHS' Administration for Children and Families take action on Head Start centers that have child safety incidents?

- Yes. Head Start grant recipients are required to immediately report any significant child safety incident to HHS. ACF recently clarified reporting requirements in program guidance. Following the report of an incident, ACF initiates a review to compile all evidence and facts surrounding the incident.
- Between 2016 – 2020, 95 percent of recipients who received a finding for a child safety incident demonstrated they corrected the issues that led to the incident. ACF will act to terminate the grant of a grantee that fails to correct the issue. More than one finding, failure to report, or failure to correct a serious or systemic child safety incident requires Head Start programs to compete for continued funding when the grant period ends.
- Staff and contractors who are found in violation of child safety policies are regularly disciplined or terminated by their Head Start agency.

Q: Were the teachers or administrators involved in the incidents called out in the report terminated or otherwise disciplined by ACF or their direct employer?

- ACF and individual Head Start programs take any incident that jeopardizes child safety very seriously. In most cases the employment of the staff persons involved directly in the incidents was terminated.
- Every Head Start agency must make systemic corrections for any incidents that occur with their program in a timely fashion. Often staff failings are evidence of broader systemic failures which must be corrected to ensure all children are kept safe. Grant recipients who do not demonstrate serious and timely commitments to correcting their safety systems risk immediate suspension of federal funding.

Q: How is ACF working to make sure children are safe in their programs?

- All children should have the opportunity to thrive and reach their full potential in safe and healthy settings that prepare them for school and life. While serious child safety incidents have occurred in Head Start programs, annually just 0.01% of children who attended Head Start programs from 2016-2020 were impacted by a serious incident.
- At the same time, ACF continues to prioritize efforts to improve the protection of children's safety. ACF takes a proactive approach to protecting child safety, providing technical assistance and training on supervision, preventing child abuse, and implementing policies and procedures to protect children.
- Head Start Program performance standards outline rigorous standards that must be met to ensure every child's safety. When an incident does occur, Head Start programs are required to report incidents to ACF, as well as state licensing and child protection agencies as appropriate.

- When child safety incidents are reported, ACF mobilizes resources to support the child and family involved, as well as to help the Head Start agency identify and remediate systemic failures that led to the incident.

Q: Why should Congress continue to fund a program that fails to keep all children safe?

- Head Start programs continue to be the gold standard for early childhood education and safety. Child safety incidents are rare, thanks to our robust federal oversight and rigorous health and safety requirements which support high quality services, as well as credentialed teachers and staff serving each of our centers.
- Head Start programs provide children one of the best starts in life. The Head Start program is a leader when it comes to early childhood practice related to infant mental health, parenting, dual language learning, curricular enhancements, caregiver-child interactions, dual-generation approaches, and other areas.
- Head Start programs serve nearly 1 million children and their families each year in urban, suburban, and rural areas in all 50 states and DC.

BACKGROUND:

In September 2022, HHS OIG released a report that found approximately one in four Head Start grant recipients received an adverse finding from ACF for child abuse, lack of supervision, or unauthorized release between October 2015 and May 2020. These adverse findings encompassed 1,029 individual incidents. Additionally, Head Start grant recipients did not promptly self-report all incidents of child abuse, lack of supervision, and unauthorized release as required.

Additionally, the GAO released a report in 2010 that found potential fraud and abuse at select Head Start centers. In 2019, GAO released a follow up to the first report highlighting that action was still needed to enhance program oversight and mitigate significant fraud and improper payment risks. GAO had attempted to enroll fictitious children in Head Start centers using information that should have disqualified applications, including pay stubs that exceeded income requirements.

Head Start - Vaccine Mandates

TALKING POINTS:

- Head Start programs are critical supports for families and children and we are committed to ensuring they remain safe and open.
- Program closures create instability for vulnerable families who depend on the program, impede Head Start families from participating in the workforce, and impose financial hardship on low wage workers.
- In January 2023, ACF published its evidence-based Final Rule on COVID-19 mitigation, which removed the universal masking requirement but did not change vaccination or testing requirements. The vaccine and testing requirements remain under review until a final rule is published to address those provisions of the Interim Final Rule with Comment Period
- The CDC continues to recommend that children ages 6 months and up be vaccinated against COVID-19. Vaccination remains the most effective way to protect individuals and the people they live and work with from getting COVID-19 – especially in care settings like Head Start.

Program Information

BACKGROUND:

The requirement for the COVID-19 mitigation policy, which must be in place by March 7, 2023, will be formally monitored beginning in the 2023–24 program year. OHS will collect data related to the development of a mitigation policy from a random sample of grant recipients in the spring 2023. The vaccine and testing requirements remain under review until a final rule is published to address those provisions of the Interim Final Rule with Comment Period.

Health Exchange Fraud

- HHS is committed to protecting taxpayer funds while balancing the burden on consumers, employers, and other individuals and entities involved in the Federally-facilitated exchange (FFE) and State-based exchanges (SBEs).
- As such, HHS has implemented a number of strategies to oversee the program integrity of Advance Payments of the Premium Tax Credit (APTC) to prevent and address instances of potential fraud.

Specifics

- As previously recommended by the GAO, HHS completed an Exchange Fraud Risk Assessment, leveraging the GAO's fraud risk framework. HHS has used this framework to identify and prioritize key areas for potential risk and mitigation activities in the Federally-facilitated exchange.
- In November 2022, HHS announced the first improper payment rate for APTC made using the Federally-facilitated exchange platform, which was less than one percent (0.62 percent) for Benefit Year 2020.
- HHS requires State-based exchanges to conduct a defined set of oversight activities, and tracks and monitors how State-based exchanges establish program integrity standards that comply with Exchange-related policy and operational requirements set forth in statute, regulations, and guidance.
- CMS regulations specify a set of eligibility verification requirements that all Exchanges, including State-based exchanges, must follow. These regulations, developed and finalized through a public comment process, allow flexibility for certain eligibility verification requirements as to how Exchanges should meet the relevant verification requirement.
- HHS monitors State-based exchange compliance with program integrity standards through numerous means, including requiring SBEs to submit annual independent external programmatic audits conducted by an independent auditing entity. State-based exchanges must inform HHS of any audit findings and submit corrective action plans to address open findings. HHS reviews the audit results and monitors open audit findings until they are resolved.
- Finally, all State-based exchanges are required to submit documented plans demonstrating that they have a comprehensive oversight and monitoring program to ensure program integrity, which includes policies and procedures to identify incidents of fraud, waste, and abuse, as required under Section 1313(a)(5) of the ACA.

Hepatitis C

(Dollars in Millions)

	FY 2024	FY 2024-2028 (5-year)	FY 2024-2033 (10-year)
National Hepatitis C Elimination Program Cost	1,134	11,337	11,337
Medicare Impact	183	1,177	984
Medicaid Impact	-1,130	-6,330	-7,180
National Hepatitis C Elimination Program Net Cost	-187	6,184	5,141

TALKING POINTS:

- **Eliminate:** We can eliminate hepatitis C in the United States over the next 5 years at minimal cost. The program will expand screening, testing, treatment, prevention, and monitoring of hepatitis C from 418,000 to 1.5 million individuals with a goal of eliminating hepatitis C in the United States.
- **Equity:** More than 2 million Americans are chronically infected with hepatitis C, including a disproportionate number of non-Hispanic Black and American Indian and Alaska Native individuals, who also experience other health disparities.
- **Rising rate of infection:** From 2010 to 2020, rates of acute hepatitis C quadrupled among adults aged 20–39 years, mirroring increasing rates of overdose deaths fueled by the nation’s opioid and methamphetamine crises.
- **Curative Treatment:** Untreated, hepatitis C can cause advanced liver disease, liver cancer, and death. An 8 to 12-week course of oral direct acting antivirals cures hepatitis C in more than 95% of people. Curative treatment prevents ongoing transmission, reduces the incidence of liver cancer, saves lives, and is cost effective.
- **Prevention:** Implementation of the program will increase the number of people treated for hepatitis C from 418,705 to 1,500,452 over 5 years, preventing hundreds of thousands of severe illnesses, tens of thousands of serious complications, and many thousands of lives over the next decade – at minimal net cost.

QUESTIONS:

Q: How will this program work?

A: The Program includes a national subscription model to expand access of direct acting antivirals to Medicaid beneficiaries, justice-involved populations, uninsured individuals, and American Indians and Alaskan Natives receiving care through the Indian Health Service, tribal health, or urban Indian health programs. The subscription model will include all manufacturers that offer competitive prices.

For Medicaid beneficiaries, the federal government will pay 100% of the medication costs through the subscription program. The medications will be made available through established

distribution channels, including mail order pharmacies, retail pharmacies, and 340B hospital and clinic pharmacies. The model will include a low burden eligibility check, likely at the provider level, to avoid waste, errors, and fraud.

For Medicare beneficiaries, the federal government will cover 100% of cost-sharing for all Medicare Part D beneficiaries receiving covered treatment. Medicare will also adopt a program of quality measurement and improvement to drive uptake of hepatitis C testing and treatment.

Private insurers will be required to cover hepatitis C testing and curative hepatitis C treatment by reducing coverage denials and meeting network adequacy requirements. Insurers will also limit out-of-pocket costs for these medications; for example, by including coverage prior to the deductible being met.

Q: Is this a cure for hepatitis C?

A: There is still no vaccine for hepatitis C. The program will include support for vaccine research and preventive services, which has been shown to reduce reinfection rates substantially.

Q: How will HHS identify and attract currently infected individuals to get screened, tested, and treated?

A: The Program will substantially expand screening strategies and settings, especially for high-risk populations. For instance, it will support universal screening in primary health care settings as part of routine care, including through automatic prompts to clinicians in electronic health records.

The program will also develop educational resources for providers and the public to increase awareness of hepatitis C, screening recommendations, and treatment options.

Other approaches will include expanding the number of providers who can screen and treat hepatitis C using proven and innovative telehealth methods and increasing the number of community health workers and case managers who can successfully link people to care. CDC and HRSA will provide grants to state and local health departments to support the funding for community-based providers. The Program will also support mobile treatment capabilities.

The Program will accelerate the commercialization of diagnostic tests that are available outside of the United States, specifically point-of-care RNA diagnostics and hepatitis c virus core antigen laboratory assays.

Q: How many non-Hispanic Black and American Indian and Alaska Native individuals, experience other health disparities?

A: Hepatitis C disproportionately affects certain populations, many of which experience other health and social inequities -- including those who are uninsured, American Indian and Alaska Native persons, non-Hispanic Black persons, those caught up in the opioid crisis, and baby

health records. boomers who were infected in pre-1993 blood transfusions. From 2010 to 2020, rates of acute hepatitis C quadrupled among adults aged 20–39 years, mirroring increasing rates of overdose deaths fueled by the nation’s opioid and methamphetamine crises.

Q. Which parts of HHS will carry out the work on this program?

A: The Office of the Assistant Secretary for Health (OASH) will administer and coordinate this whole-of-government program. With a robust organizational structure in place, OASH is well positioned to ensure cross-departmental and intergovernmental collaboration and transparency. In similar capacity, OASH also leads and coordinates a cross-agency, federal government-wide the Ending the HIV Epidemic in the U.S. (EHE) initiative. OASH will also be responsible for providing an annual report to Congress.

Program Information

- **The Budget of \$11.3 billion provides funding to eliminate hepatitis C in the United States to be allocated over five years. The overall net cost of the proposal across all accounts is \$5.1 billion.**
 - The 5-year program has 3 main components:
 - Accelerating the availability of Point-Of-Care (POC) diagnostic tests
 - Providing broad access to curative hepatitis C medications
 - Increasing implementation efforts
 - Medicare Net Costs: \$1 billion over ten years, while creating estimated net savings to Medicaid of \$7.2 billion over 10 years, including reduction in health care costs by prevention of downstream illness.
 - The overall net cost to the federal government across all accounts is \$5.1 billion over 10 years.

HIPAA

TALKING POINTS:

- Ensuring individuals have access to their health information and protecting patient privacy is of the upmost importance.
- OCR expects to receive over 33,000 HIPAA complaints this year and has seen an increase in large breaches (over 500 people).
 - HIPAA complaints increased 39 percent from 2017 to 2022; HIPAA breach cases alone have increased 259 percent during the same time.
- OCR's proposed budget increase to \$78 million will also allow the division to fully enforce the law and keep up with the growing workload of cases through hiring additional investigators.
- OCR is also currently engaged in the rulemaking process on the HIPAA Privacy Rule, which established federal standards for the protection of protected health information, and we look forward to your feedback during that process.

IHS - Provider Abuse

TALKING POINTS:

- There is no more important priority at IHS than the protection of patients – especially our most vulnerable patients – from abuse and instilling a culture of accountability. IHS must be able to continue to foster trust and instill confidence in the communities it serves.
- IHS has taken strides to increase safety across the board during this Administration.
 - The IHS Anti-Abuse policy is nearing completion. This policy will increase protection for all patients, and will cover all employees, and all types of abuse.
 - The IHS is developing and implementing a uniform credentialing and privileging policy.
 - The IHS has also fully implemented Safety Tracking & Response (I-STAR) across the Agency to provide real time data on any reported provider abuse, which will result in immediate action to investigate any provider abuse allegations.
- We can still do more. We continue to review our systems and identify gaps that could lead to vulnerabilities. IHS is committed to working with Congress, HHS OIG and local enforcement agencies, and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of the patients under our care. The budget includes an additional +\$12 million for IHS Direct Operations to support critical management and oversight functions at IHS, including implementing recommendations to prevent abuse and ensure patient safety.

QUESTIONS:

Q: Can you speak to the lessons learned after the Dr. Weber tragedy?

My heart goes out the victims of this unfortunate tragedy. Abuse and other forms of criminal misconduct should not be tolerated

HHS Employees are encouraged to report any suspected unethical or criminal behavior. Any transgressions that endanger the people we serve or violate the public trust will be held accountable.

We are committed to maintaining transparency with Congress as IHS and other HHS officials work to implement important and necessary changes to ensure the safety of our workplace and patients.

The safety and wellbeing of children in the care of HHS is among our most important responsibilities and we will continue to be vigilant.

Q: What does IHS have to say to the victims of provider abuse?

- The IHS acknowledges the trauma suffered by the victims of sexual abuse within our agency is unacceptable. These actions are reprehensible, and we sincerely regret the harm caused to those involved.
- We will do all we can to improve and sustain the culture of care throughout the IHS. The agency is committed to working with Congress and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of every child. Together, we are moving forward in delivering quality care to achieve the IHS mission to raise the physical, mental, social and spiritual health of American Indians and Alaska Natives to the highest level

Q: What are the 11 actions that IHS intends to accomplish with the goal of removing IHS from the GAO's High-Risk List?

Misconduct and Performance Policy and Training Review
Design Governing Board Standardization
Assess Needs of Patient Populations
Document Oversight of Facility Budgets
VA and IHS MOU Performance Measures
Strategic Plan Implementation and Progress Tracking
Improve Internal Communications
Document Oversight of Leadership Training
Design a Policy Review Process
Create a Culture of Compliance
Improve Oversight of Regional and Area Human Resources Offices

IHS - Advance Appropriations

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Total IHS Funding	7,105	9,650	+2,545*

* Represents an increase of 36% over FY23 enacted

TALKING POINTS:

- We are especially grateful for your work providing IHS advance appropriations in the FY 2023 bill – this was truly a historic achievement that will greatly improve the lives of Native American families throughout Indian country.
 - Indian Country has been asking for more stability to address the persistent health disparities suffered by AI/ANs, and together, we finally delivered.
- Advance appropriations represent an important step towards securing stable and predictable funding to improve the overall health status of AI/ANs, and ensuring that the disproportionate impacts experienced by tribal communities during government shutdowns and continuing resolutions are never repeated.
 - We are already seeing the benefits of advance appropriations in action – we have heard from health facilities about benefits in improved planning and staff job security.
- IHS remains committed to upholding promises it has made to both Congress and Indian Country to continue to increase accountability and improve the quality of care for patients.

QUESTIONS:

Q: What about mandatory funding?

- Looking beyond this budget year, the Administration continues to support full mandatory funding for IHS as the more appropriate long-term funding solution for the agency.
- We will continue to work collaboratively with Tribes and Congress to move toward sustainable, mandatory funding.
- Until this solution is enacted, it is critical that Congress continue to prioritize advance appropriations for IHS through the discretionary appropriations process to ensure funding for healthcare services and critical facilities activities are not disrupted.
- Beginning in FY 2025, the budget would make all funding for IHS mandatory. Funding would grow automatically to account for a number of factors.
 - We believe that a change of this magnitude is needed to meet the moment and deliver for Indian Country.

Program Information

BACKGROUND:

IHS has been chronically under-funded compared to other health systems in the country. These funding disparities directly contribute to stark health disparities.

- AI/AN people born today have a life expectancy nearly 11 years less than all other races in the U.S., as well as increased morbidity rates. The pandemic has only exacerbated these issues.

The House and Senate Appropriations Committees were hesitant to support advance appropriations because there were significant challenges and issues implementing advance appropriations at the Veterans Affairs Administration. There were also concerns with providing advance appropriations to IHS because it has been on the GAO High Risk list for many years with outstanding recommendations. IHS also has a history of oversight failures related to provider abuse.

IHS – Contract Support Costs

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Contract Support Costs*	969	1,168	+199

*The budget proposes mandatory funding for Contract Support Costs in FY 2024

TALKING POINTS:

- We are aware of recent court rulings that would require IHS to pay Contract Support Costs on portions of Tribally-operated Health Programs funded by third party revenues like Medicare and Medicaid reimbursements.
- This change could significantly increase the amount of Contract Support Costs that IHS provides to Tribally-operated Health Programs.
- If these rulings are upheld, HHS will work to implement them as expeditiously as possible.

QUESTIONS:

Q: Does the FY 2024 Budget take the cost of implementing these rulings into account?

- The funding estimate for Contract Support Costs in the budget does not reflect the impact of implementing the 9th and 10th circuit court rulings, as they are not yet settled case law.
- HHS is actively monitoring the situation and analyzing potential costs. We will keep Congress apprised of any changes in Contract Support Costs as a result of the rulings.

IHS - High-Risk List

TALKING POINTS:

- IHS is committed to addressing and correcting past failings. We also remain committed to transparency and accountability and are continually working to sustain and improve the culture of care throughout the Agency.
- In 2021, IHS developed an action plan to meet the GAO's criteria for removal from its high-risk list. Since that time, the agency has been working to address actions to accomplish by the end of June 2023. IHS leadership is committed to making progress on addressing GAO's recommendations. These efforts built the foundation for the agency's 2023 work plan.
- The Department and the Agency are committed to working with Congress and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of every patient. Together, we are moving forward in delivering quality care to achieve the IHS mission to raise the physical, mental, social and spiritual health of American Indians and Alaska Natives to the highest level.

QUESTIONS:

Q: What are some of the actions that IHS intends to accomplish with the goal of removing IHS from the GAO's High-Risk List?

Misconduct and Performance Policy and Training Review
Design Governing Board Standardization
Assess Needs of Patient Populations
Document Oversight of Facility Budgets
VA and IHS MOU Performance Measures
Strategic Plan Implementation and Progress Tracking
Improve Internal Communications
Document Oversight of Leadership Training
Design a Policy Review Process
Create a Culture of Compliance
Improve Oversight of Regional and Area Human Resources Offices

Q: GAO highlighted that IHS faces workforce challenges; their overall vacancy rate for clinical care providers was 25 percent at one point. What has IHS done to resolve this issue?

- IHS has strengthened its relationship with academic institutions through fellowships, residencies and clinical rotations that attracted talented practitioners focused on generating positive change in Indigenous communities.
- IHS signed a new MOU with the VHA aimed at improving the health status of AI/AN veterans.

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- IHS has supported public health workforce activities to bolster the capacity of tribal communities to respond to future emergencies.

Q: What has IHS done to address some of the concerns with personnel processes and systems?

- Implemented a nationwide electronic provider credentialing system that modernizes provider credentialing and privileging within federally-operated hospitals and clinics.
- Implemented an employee relations case tracking system to manage nationwide employee relations activities.
- Implemented an electronic Security Manager System to track personnel background investigations.
- Established a standardized procedure for determinations of unsuitability from a background investigation.

Program Information

BACKGROUND:

Between 2019 and 2021, IHS received recommendations from IHS commissioned internal reviews and external entities on the design and implementation of IHS policies and processes established to protect patients and to hold employees accountable for compliance. The IHS concurred with OIG and GAO recommendations and submitted plans for corrective actions. In 2021, IHS developed a targeted action plan to meet the GAO's criteria for being removed from their high-risk list, which IHS was placed on in 2017. The IHS also initiated strategies to address prior recommendations from the Presidential Task Force on Protecting Native American Children in the Indian Health Service System.

Institution for Mental Disease (IMD) Waivers

TALKING POINTS (IMDs AND CRISIS STABILIZATION):

- Strengthening behavioral health care is a top priority for the Biden-Harris Administration. That's why last year, as part of the National Tour to Strengthen Mental Health, I traveled along with other HHS leaders across the country to hear directly from Americans about the mental health challenges they're facing and engage with local leaders to strengthen the mental health and crisis care systems in our communities.
- Under current law, Medicaid generally does not pay for services rendered to beneficiaries aged 21 to 64 who are patients in psychiatric institutions with more than 16 beds, referred to in Medicaid as "institutions for mental disease" (IMDs).
- Crisis stabilization services are critical to those experiencing a behavioral health crisis, and HHS shares your goal of ensuring Medicaid beneficiaries have access to a continuum of crisis stabilization services. CMS has worked within the confines of the law to provide states with flexibility to increase access to these services. For example,
 - o CMS has approved Medicaid section 1115 demonstrations that allow state Medicaid programs to pay for services provided to individuals with serious mental illness or serious emotional disturbance or substance use disorder who are short-term residents in an IMD.
 - o Similarly, managed care organizations are permitted to reimburse up to 15 days per month of treatment in IMDs.

If Pressed on Qualified Residential Treatment Programs

- Children in foster care should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. CMS is committed to ensuring children with unique health needs receive high-quality care in the most appropriate setting permissible under the law.

QUESTIONS:

Q: Are crisis stabilization programs subject to the Medicaid IMD exclusion?

- Each state is responsible for determining whether a facility is an IMD. If a state Medicaid agency determines that a facility is an IMD, federal financial participation generally would not be available for any services provided to Medicaid beneficiaries ages 21-65 while residing in that facility. Medicaid does permit payment for inpatient psychiatric hospital services provided to those over the age 65 or under the age 21.

Q: Can you explain how the IMD exclusion doesn't violate parity laws? Enrollees are covered if they stay in non-psychiatric facilities that have more than 16 beds. Are private insurance plans allowed to make this exclusion?

- The payment exclusion for Medicaid services provided to beneficiaries in IMDs is a statutory prohibition established by the Congress in 1965 and therefore beyond the scope of existing HHS authority. Under this broad exclusion, federal financial participation is generally unavailable for the cost of services (regardless of whether the services address physical or mental health) provided either inside or outside the IMD while the individual is a patient in the facility. The full

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range of covered services, including mental health and substance use disorder services, could be paid by Medicaid when beneficiaries are in facilities that are not IMDs

Q: Do you believe that children in Qualified Residential Treatment Programs with more than 16 beds should be able to keep their Medicaid coverage?

- Children should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. Placement in a Qualified Residential Treatment Program that is an IMD does not impact Medicaid eligibility.
- While the Medicaid statute prohibits states from receiving federal financial participation for services delivered to most individuals residing in an IMD, states can apply for a time-limited serious mental illness/serious emotional disorder 1115 demonstration to receive Medicaid payment for services provided to children in Qualified Residential Treatment Programs with more than 16 beds.

Program Information

Medicaid Waivers for the Institution for Mental Disease (IMD) Payment Exclusion:

- Under current law, Medicaid is prohibited from paying for services provided to Medicaid enrollees aged 21 to 64 who are residing in psychiatric institutions with more than 16 beds - referred to in Medicaid as “institutions for mental disease” (IMDs). This restriction is known as the Medicaid IMD exclusion.
- However, states can participate in a serious mental illness/serious emotional disturbance or substance use disorder Medicaid 1115 demonstration initiative.^[1]
 - Under these demonstrations, Medicaid is authorized to pay for services provided to individuals in an IMD, where appropriate, when states also commit to ensuring a comprehensive, coordinated system of community-based care.
 - To date, CMS has approved serious mental illness/serious emotional disturbance IMD expenditure authority under this demonstration initiative in 9 states and DC (*States: AL, DC, ID, IN, MD, NH, OK, UT, VT, WA*)
 - CMS has approved substance use disorder IMD expenditure authority in 34 states and DC (*States: AK, CA, CO, CT, DC, DE, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MT, NC, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, UT, VA, VT, WA, WI, WV*).
 - States may also use managed care through “in lieu of” authority to cover short stay (15 day) coverage in an IMD—essentially, CMS can allow this because the managed care plan is covering the service as part of a holistic capitation rate.
- Under current law, **Qualified Residential Treatment Programs (QRTPs)** are a type of child care institution in which children are eligible to receive title IV-E foster care maintenance payments. For purpose of Medicaid payment, however, QRTPs with more than 16 beds may be considered IMDs and thus subject to the IMD exclusion.
 - States can apply for a time-limited serious mental illness/serious emotional disorder 1115 demonstration to receive federal financial participation for Medicaid-covered services provided to children in Qualified Residential Treatment Programs with more than 16 beds.
 - As a condition of approval for the exemption, states are required to provide CMS with a plan, including key milestones and timeframes, for transitioning children out of Qualified Residential Treatment Programs that are non-eligible IMDs.
 - A child maintains eligibility in Medicaid; the Q RTP just cannot receive payments.

^[1] <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf> and <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17003.pdf>

Infant Formula

TALKING POINTS:

- Ensuring that safe and nutritionally adequate infant formula is available to parents and caregivers across the country is a top priority of the Department.
- That is why during the shortages—HHS invoked the Defense Production Act to ensure rapid increase in supply. We flew in 13.7 million 8-oz bottle equivalents of infant formula, facilitated 11 flights to fly in formula to the United States, and imported more than 97.9 million 8-oz bottle equivalents of infant formula.
- FDA is focused on hiring additional staff, modernizing scientific requirements, and streamlining review processes for infant formula.
- This budget will support FDA efforts to implement new authorities provided by the FY23 omnibus including requiring prompt notifications of disruptions to manufacturing, requiring redundancy risk management plans to enhance resiliency and mitigate future supply chain disruptions, increasing the frequency of inspections, and developing a National Strategy on Infant Formula.

Perrigo Recall Talking Points:

- Perrigo, an infant formula manufacturer, recalled certain lots of its Nestle Gerber GoodStart Infant Formula produced at its Eau Claire, Wisconsin facility.
- The FDA is not currently aware of any Cronobacter-related illnesses associated with the recalled products.
- The recall is the result of a recent FDA inspection at the facility where investigators discovered the company found Cronobacter in products it produced in January. The agency also learned that other products were produced at the facility in the same timeframe and the agency did not have confidence, based on the manufacturing procedures, that the product was contamination free.
- We don't expect this recall to have a significant impact on current powdered infant formula supply. The Administration has worked to strengthen the infant formula supply chain by providing more products options for parents and caregivers.
- Earlier this month [March 8], FDA sent a letter to the infant formula industry asking for voluntary notifications of products that tested positive for certain types of bacteria and has not left the company's control. The FDA is seeking, but currently does not have, authority from Congress to require infant formula manufacturers notify the agency with this information.

QUESTIONS:

Q: How will FDA ensure the infant formula crisis does not happen again?

- FDA continues efforts to ensure the availability of safe, nutritious infant formula.
- The FY 2024 President's Budget includes a request for an additional \$10 million, for a total of \$21million, to support additional hiring of staff, as well as IT investments to better address current and emerging infant formula safety and supply issues.
- This budget will support FDA efforts to implement new authorities provided by the FY23 omnibus including requiring prompt notifications of disruptions to manufacturing,

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requiring redundancy risk management plans to enhance resiliency and mitigate future supply chain disruptions, increasing the frequency of inspections, and developing a National Strategy on Infant Formula.

- FDA also released a transition plan guidance for industry to outline a path for interested manufacturers that are marketing infant formulas in the U.S. under enforcement discretion to bring those products into compliance with U.S. requirements, helping the U.S. continue to diversify its infant formula market. As part of this plan, the Agency also continues to exercise enforcement discretion for certain manufacturers to import safe and nutritionally adequate infant formula.
- FDA also continues to work with industry to increase the volume of infant formula through normal production channels, as well as increase its monitoring of online marketplaces for fraudulent infant formula products.
- FDA also sent a letter to the powdered infant formula industry calling for prompt action to improve processes and programs to enhance safety measures.

Q: How will FDA’s organizational changes improve its ability to oversee the infant formula supply chain and carry out its food safety responsibilities?

- FDA is implementing a new, transformative vision for the FDA Human Foods Program, which will focus on protecting and promoting a safe, nutritious U.S. food supply that more quickly adapts to an ever-changing and evolving environment.
- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Inflation Reduction Act (IRA)

TALKING POINTS:

- Thanks to the Inflation Reduction Act, we finally have the authority to get American families the lower prescription drug costs they deserve.
- At the beginning of this year, we implemented the \$35 cost-sharing cap for insulin in Medicare Part D and eliminated cost-sharing under Part D for recommended, preventive vaccines.
- We are also pleased that the IRA included a provision to expand low-income assistance and to cap Part D annual out-of-pocket drug costs at \$2,000 in 2025.
- Earlier this month, we released guidance outlining how we will approach the law's landmark provisions permitting Medicare to negotiate prices for the first time, seeking comment on many key policies.

INSULIN PRICING TALKING POINTS:

- As of this week, all three of the leading insulin producers in America have heeded President Biden's call to reduce their prices and cap the cost of insulin to \$35 per month.
- This is a major victory for seniors and working families. For far too long, American families have been crushed by drug costs many times higher than what people in other countries are charged for the same prescriptions.
- Last August, President Biden signed into law the Inflation Reduction Act, which for the first time allows Medicare to negotiate lower prescription drug prices for seniors, caps the cost of insulin at \$35. During his State of the Union, the President made clear that this life saving benefit should apply to everyone – no American should have pay more than \$35 for insulin. And he called for extending the \$35 monthly cap on insulin to all Americans.

QUESTIONS:

Medicare Drug Price Negotiation Program

Q: Won't the Medicare Drug Price Negotiation Program lead to manufacturers increasing the launch prices for new drugs?

- Manufacturers use many factors when considering their launch prices and will price their drugs at the price they believe the market will bear.
- It's also important to note that a drug cannot be eligible for negotiation until it has been FDA-approved for at least 7 years and a biological product cannot be eligible for negotiation until it has been FDA-licensed for at least 11 years.
- The Congressional Budget Office didn't estimate that the new Drug Price Negotiation program would have a significant impact on launch prices.

Q: Will drug price negotiation have a chilling effect on manufacturers seeking a second or third indication for an orphan drug?

- Drugs selected for negotiation will have been on the market for quite some time and will be high expenditure drugs.
- The law requires that at least 7 years, for drugs, or 11 years, for biologicals, must have elapsed between the selected drug publication date and the FDA approval or licensure, as applicable.
- We support innovation and believe it is vitally important that beneficiaries have access to innovative new therapies.
- Increased competition as a result of drug price negotiation will encourage drug makers to innovate in order to stay competitive and broaden their target patient populations, including orphan diseases.

Q: Won't drug price negotiation crush innovation and kill hundreds of new cures? Studies have found that the IRA's negotiation provision would kill up to 342 cures.

- We support innovation and believe it is vitally important that beneficiaries have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.
- The Negotiation Program will make drugs more affordable for people with Medicare. We're also expecting negotiation to encourage drug makers to create business models to stay competitive, fostering the development of new treatments and delivery methods.

Q: What concrete steps does the Administration plan to take in order to implement and enforce the legislation's ban on the use of discriminatory comparative effectiveness research (i.e., QALYs)?

- The law requires that we not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who are elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. We will follow the law.

Medicare Part B and Part D Inflation Rebates

Q: How will HHS plan for and respond to drug shortages or severe supply chain disruptions of Part B and Part D rebatable drugs?

- The law requires CMS to waive or reduce the inflation rebate when drug shortages or certain supply chain disruptions occur.
- CMS is soliciting comment on this issue, and intends to design a final policy that preserves access, while not creating perverse incentives for drug companies to sustain or create drug shortages.

Q: Won't the Medicare Prescription Drug Inflation Rebate Program lead to manufacturers increasing the launch prices for new drugs?

- Our understanding is that manufacturers use many factors when considering their launch prices and price their drugs at the price they believe the market will bear.
- For too long, Americans have faced skyrocketing prescription drug prices.

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- Thanks to the law, prescription drug companies will pay a rebate for increasing their prices above inflation, paid into the Medicare Trust Fund.
- This policy will strengthen the Medicare program for generations to come.

Q: Are 340B acquired units being removed from the Part D inflation rebates?

- The Inflation Reduction Act sets clear parameters and timeframes for how to treat 340B drugs as HHS implements inflation rebates. We will follow the law.
- The Inflation Reduction Act requires that 340B units be excluded from calculating Part D inflation rebates beginning in 2026. We will follow the law.

Implementation Funding

Q: How is HHS planning to spend the \$3 billion in implementation funding provided by the Inflation Reduction Act for the Drug Price Negotiation Program?

- We're still in the early stages of the implementation process.
- The new Drug Price Negotiation Program requires a great deal of new work by CMS.
- We're using the funding to hire new staff, bring on contractors, and develop and modify systems.
 - Internal Information: To date, CMS has spent \$45 million (FY 2022 and so far in FY 2023). ASFR is working with CMS to have a long-term spend plan. The breakdown is below:

IRA Sections	FY 2022 Actuals	FY 2023 Spend plan	FY 2023 Obligations
Section 11004	\$ 1,702,272	\$ 124,291,357	\$ 23,009,975
Section 11101	\$ 3,197,048	\$ 15,743,023	\$ 4,158,849
Section 11102	\$ -	\$ 12,037,324	\$ 1,722,262
Section 11201	\$ 3,726,526	\$ 48,743,155	\$ 3,534,535
Section 11202	\$ -	\$ 10,555,586	\$ 2,293,231
Section 11406	\$ 1,500,000	\$ -	
Total	\$ 10,125,846	\$ 211,370,444	\$ 34,718,852

- This information is part of an open Oversight request from the Committee on Energy and Commerce. The information is not public yet, but a response with the above information will be provided prior to next week's hearing with this committee.

Q: What specific measures does the administration plan to undertake in order to prevent waste, fraud, and abuse with respect to the implementation funding?

- We take our responsibility to protect taxpayer dollars very seriously. We are vigilant about how we are spending the funding to head off waste, fraud, and abuse, just as we do with implementing other programs.

Insurance Affordability and Coverage Gap

TALKING POINTS:

- The Biden-Harris Administration is committed to keeping high-quality healthcare coverage affordable, accessible, and permanent for all Americans.
- The Affordable Care Act has reduced the number of uninsured Americans to an all-time low and enhanced subsidies extended by the Inflation Reduction Act have made Marketplace coverage even more affordable and accessible for millions of Americans.
- Building on these successes, the budget makes permanent the enhanced premium tax credits so that consumers can keep high-quality, low-cost coverage.
- This budget extends coverage to the 2 million low-income individuals in states that have not expanded Medicaid by providing \$200 billion for a Medicaid-like coverage option.

QUESTIONS:

Q: How exactly would HHS close the coverage gap in States that have not expanded Medicaid?

- The budget would fulfill the intention of the Affordable Care Act by providing premium-free plans to individuals below 138 percent of the poverty level in states that have not expanded Medicaid, potentially decreasing the number of uninsured individuals by over two million.

Q: What is the Administration doing to make health insurance more affordable for Americans?

- The enhanced premium tax credits, which were extended through 2025 under the Inflation Reduction Act, have played a vital role in making coverage more affordable for millions of Americans by eliminating the required premium contribution for very low-income individuals and families and limiting the maximum income contribution towards benchmark Marketplace plans to 8.5 percent of income.
- The enhanced premium tax credits also made coverage more affordable for the middle-class by lifting the eligibility cap for these tax credits, which was previously set at 400 percent of the poverty level.
- Also, in 2022, the Administration finalized regulations that fixed the “family glitch,” which finally closed a loophole that prevented over a million Americans from obtaining coverage or seeing their coverage become more affordable.

Q: What will HHS do to make sure that uninsured Americans know about these affordable coverage options?

- The Biden-Harris Administration has quadrupled the number of Navigators to help hard-to-reach and traditionally marginalized groups enroll in quality, affordable coverage.

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- HHS has invested over \$1.2 billion into Navigators and outreach campaigns since 2021, which connected people with high-quality, affordable health care. These historic investments have helped result in the lowest uninsured rate in our nation’s history.
- In this budget proposal, we are doubling down on these investments to ensure people get the insurance they need by allocating \$141.2 million available for Navigators and Assisters and budgeting over \$280 million for other forms of outreach.

LGBTQ Youth

TALKING POINTS:

- Gender affirming care is a standard of care recognized by every major medical association, which included 1.3 million providers. It's also mental health and suicide prevention.
- The current medically-accepted standard of care, WPATH SOC8, was developed by the top medical and scientific experts in transgender health.
- The ideologically-driven attacks on gender-affirming care do not account for the best available science and evidence on appropriate healthcare services for transgender people.
- Likewise, gender affirming care is an integral part of child centered welfare programs especially those for vulnerable children and youth. This budget supports prohibiting child welfare agencies from discriminating against current or prospective foster or adoptive parents or a child in foster care on the basis of sexual identity, gender identity, or expression.

QUESTIONS:

Q: What is a woman?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- Support youth and families; HHS commitment to advance safety and support for LGBTI+ youth. Access to gender affirming care, when medically necessary can be lifesaving.
 - Ensuring such access is the law.

Q: How many genders are there?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- At HHS, we are committed to advancing health equity for people of all genders. Health equity is defined by HHS Healthy People 2030 as the “attainment of the highest quality of health for all people.” We work toward that goal every day.

Q: Does HHS support irreversible genital surgeries on children?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

Q: Is HHS funding gender affirming care?

- The Department is committed to removing discriminatory barriers to coverage for all because it can lead to improved health outcomes for all, including those in the LGBTQI+ community.
- HHS will continue to interpret and enforce section 1557 of the ACA and its protections against sex discrimination to prohibit discrimination on the basis of sexual orientation and gender identity in all aspects of health insurance coverage to which Section 1557 applies.

Q: Does HHS support “biological boys” playing on girls sports teams?

- In my role as Secretary of Health and Human Services, I am focused on making sure people have health care, period. HHS does not have a role in youth sports.
- [Optional]: The harm caused by these state laws is very clear: trans youth are more likely to experience social isolation, loneliness, depression, and are more likely to utilize tobacco, alcohol, and other drugs – all of which we know are decreased by participation in school sports.

Q: Does HHS support irreversible and experimental medicine on children such as puberty blockers?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

Program Information

BACKGROUND

- In 2021, President Biden signed an Executive Order Advancing Equality for LGBTQI+ Americans.
- Our Department has historic deliverables under this Executive Order including:
 - deliverables to safeguard LGBTQI+ youth from the harms of conversion therapy,
 - addressing discrimination and barriers faced by LGBTQI+ children, youth and families in the child welfare system and juvenile justice systems,
 - strengthening support for LGBTQI+ older adults, including those that live in Long Term Care facilities,
 - advancing health equity for intersex individuals.
- HHS is working diligently to fully implement the President's executive order and is working through a department-wide LGBTQI+ Coordinating Committee to advance policies that improve the health and wellness of LGBTQI+ people who live in America.
- We are also working to implement President Biden's National HIV/AIDS Strategy, which calls for an expansion of PrEP utilization, support for harm reduction strategies, and calls for reform to state HIV criminalization laws.
- Expanding PrEP access and reducing disparities in PrEP access remain critical to ending the HIV epidemic in the United States, and the federal government can't achieve this alone – we need the partnership of states like California to join us in prioritizing access to PrEP for everyone who needs it.
- Finally, from President Biden and Vice President Harris, to myself and the entire team at HHS – we are committed to advancing health equity in all policies. Healthy People 2030 defines health equity as “the attainment of the highest quality of health for all people” and that is a goal we strive toward every day.

Q: HHS has published documents promoting unproven medical treatments for young people that you have referred to previously as gender affirming care. Does HHS intend to use its budget going forward to promote unscientific treatments?

- Major medical associations in the United States, including the American Medical Association, the American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, the Pediatric Endocrine Society, and the Society for Adolescent Health and Medicine, hold that gender-affirming care is medically necessary, safe, and effective care for transgender and nonbinary children and adolescents. Such care may include counseling, hormone blockers, hormones, surgery, or other services that a medical provider determines to be in the best interest of an individual patient.
- Research has shown that access to gender-affirming care improves health outcomes and overall well-being of children and adolescents who are able to access it. This is critically important because gender diverse youth face significant health disparities if they are unable to find support, undermining health equity.
- HHS considered this substantial body of evidence before publishing documents related to gender-affirming care. By acting in accordance with the overwhelming expert consensus about gender-affirming care, HHS supports the rights of individuals to access medically necessary care without discrimination.

LIHEAP/LIHWAP

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Base Funding	4.0B	4.1B	+111M
Supplementals	2.1B	100M	-2.0B
Total LIHEAP Program Level	6.1B	4.1B	-1.9B

* LIHWAP's last funding was in FY21 at \$638 million under the Consolidated appropriations Act of 2021. The American Rescue Plan appropriated an additional \$500 million in emergency funds to LIHWAP

TALKING POINTS:

- We recognize that LIHEAP is an essential program for Americans, especially for older adults and people with disabilities who are particularly vulnerable to the effects of cold.
- Likewise, LIHWAP benefits vulnerable households that pay the greatest proportion of their income towards their home drinking water and wastewater services. Water, heat, and especially in a changing climate – cooling – are basic human rights that the Department is proud to help make accessible for all.
- We have made historic investments in the program during the Biden Administration.
 - In FY2023, Congress appropriated more than \$6.1 billion for LIHEAP.
 - In the past month we have disbursed over \$1.5 billion of these funds to our 206 LIHEAP grant recipients – a lifeline for many seeing record cold and snowfalls this winter.
- The Budget requests \$4.1 billion for LIHEAP, an increase of \$111 million in base funding compared to FY 2023
- We are looking forward to continuing to partner with you to ensure we meet the critical mission of these programs by providing it with strong funding levels.

QUESTIONS:

Q: There has been some reporting and concern that states will not be able to spend their LIHWAP disbursements in time and leave money on the table. Can you speak to what the Department is doing to support states in this effort?

- We are conducting Spend Down Calls with each state, to provide TTA and help identify solutions to maximize spending when needed. We want to make sure states know about and are able to talk through promising practices that can help increase their spending rates before we take back any funding for reallocation.

Q: Why did it take HHS a couple of months to release these funds?

- The delay in releasing the funding is largely due to the fact LIHEAP funding was split across multiple funding streams in the final budget, including three different supplementals.
- HHS worked to find the most efficient and expedient way to release funding while minimizing the reporting burden to the grant recipient to the greatest extent possible.

Program Information

BACKGROUND:

LIHEAP provides heating and cooling assistance to low-income households through formula grants to states, tribes, and territories. This assistance protects vulnerable families' health in response to extreme weather and climate change. States typically make payments to home energy vendors, such as public utilities, on behalf of eligible households. Preliminary FY 2021 data shows an estimated 4.9 million households received heating assistance and nearly 60,000 households received weatherization assistance funded by federal LIHEAP dollars. Common weatherization measures including sealing air leaks, adding insulation to walls and attics, and repairing heating and cooling systems.

Since the Low Income Household Water Assistance Program (LIHWAP) expires at the end of FY 2023, the budget proposes to expand LIHEAP to advance the goals of both LIHEAP and LIHWAP. Specifically, the budget increases LIHEAP funding and gives states the option to use up to 2.7% of their LIHEAP allocations to provide water bill assistance to low-income households. If all states used 2.7% for water assistance, \$4 billion would remain available for LIHEAP. The budget additionally increases the federal administrative set aside in order to strengthen grants management, data collection, program evaluation, information systems, and outreach.

Long Term Care

TALKING POINTS:

- The budget invests an additional \$150 billion in Medicaid home and community-based services over 10 years, enabling older adults and people with disabilities to remain in their homes and stay active in their communities.
- The Medicaid investments are complemented by a robust agenda to **improve the safety and quality of nursing home care**, including efforts to improve ownership transparency, increase inspections of low-performing nursing homes, and expand financial penalties for substandard facilities.
- The budget makes a \$566 million discretionary investment in CMS's survey and certification program to provide **adequate funding for nursing home inspections** and address the backlog of complaint surveys, a \$159 million increase.

QUESTIONS:

[See CMS Medicaid Budget Summary for specific questions on Home and Community-Based Services.]

Q: CMS is proposing a number of mandatory nursing home proposals. Why is an increase in discretionary funding also necessary?

- Since FY 2015, CMS has seen an increase in the overall number of nursing home complaints and instances of high-level violations, both of which require additional survey resources. Additional resources allow CMS and state survey agencies to maintain a more proactive, rather than reactive, oversight posture that promotes patient safety and quality.

Q: Won't penalizing poor performing facilities strain resources and limit a facility's ability to provide high-quality care, further perpetuating the issue?

- Tens of billions of federal taxpayer dollars flow to nursing homes each year, and too many continue to provide poor, sub-standard care that leads to avoidable resident harm.
- Federal taxpayer dollars should not flow to nursing homes that are unsafe.

Program Information

The budget makes significant investments in **strengthening the Nation's long-term care system**, with programmatic proposals across CMS:

- **Medicaid:** Invests +\$150.1 billion over 10 years in Medicaid Home and Community-Based Service, including:
 - +\$150 billion toward promoting better pay and benefits for direct care workers to ensure an adequate workforce and support family caregivers, many of whom are too often forced out of the workforce due to the demands of caring for a loved one.
- **Discretionary:** Requests \$566 million for discretionary Survey and Certification
 - This discretionary investment is **an increase of +\$159 million** (39%) above FY 2023 enacted to maintain statutory survey frequencies for nursing homes and certain high-risk provider types, specifically hospitals and end stage renal disease facilities.
 - \$20 million of these funds would support the continued implementation of President Biden's Action Plan for Nursing Home Reform, the most ambitious set of nursing home reforms launched in decades.
- **Legislative proposals:** Includes five mandatory proposals to improve CMS's ability to oversee approximately 15,000 nursing homes nationwide.
 - The mandatory proposals on nursing homes hold facilities accountable for the care provided to those Americans who receive care in an institutional setting and enhance transparency for families seeking information on potential nursing homes.

BACKGROUND:

The Biden Administration released two Fact Sheets on Nursing Home Reform; a third is forthcoming:

- On February 28, 2022, the Administration published [Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes](#), which included a roadmap of discretionary investments, mandatory proposals, and administrative initiatives the Administration planned to undergo to improve nursing home care.
- On October 21, 2022, the Administration published [Biden-Harris Administration Announces New Steps to Improve Quality of Nursing Homes](#). This subsequent Fact Sheet focused on new actions to increase accountability of bad actors in the nursing home industry and improve the quality of nursing homes.

The most significant reform included in the above fact sheets involved the Administration's commitment to announcing federal, minimum staffing standards in nursing homes. Those proposed standards will be released this Spring, following from a comprehensive study on nursing home staffing and quality. Q&A on this proposal is included below.

March In Rights

TALKING POINTS:

- March-in authority is a powerful tool designed to ensure that the benefits of the American taxpayer's investment in research and development are reasonably available to the public.
- It is critically important for us to thoroughly understand where the boundaries of that authority lie in order to carry out that authority effectively.
- Consistent with President Biden's Executive Order on Promoting Competition in the American Economy, the Department of Commerce has not finalized any provisions on march-in rights in the proposed rule "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions" that would have prohibited the government's use of march-in rights solely on the basis of product pricing.
- As a first step in reviewing its march-in authority, Department of Commerce and the Office of Science and Technology Policy, HHS and other agencies will stand-up an Interagency Working Group to develop a framework for implementation of the Bayh-Dole march-in provision that clearly articulates guiding criteria and processes for making determinations, including where pricing is a factor in agencies' assessments.

Questions

Q: What is the total cumulative support provided by the NIH to Moderna, including for clinical trials? How much money has the US government provided to Moderna to research, develop and distribute the COVID-19 vaccine?

- HHS/NIH/NIAID has provided no direct financial support to Moderna for the development of the mRNA-1273 COVID-19 vaccine.
- NIAID scientists collaborated with Moderna to design and test the mRNA-1273 COVID-19 vaccine.
- NIH did not fund Moderna directly but NIH fully funded Phase I clinical trials through existing clinical trial networks and supported extramural institutions during OWS-funded Phase 3 clinical trials.
- Note that the COVID-19 vaccine product licensed and manufactured by Moderna contains IP beyond the patents shared with NIH. This includes IP that belongs to Moderna, e.g., the lipid nanoparticle technology.

Q: What was HHS thinking when negotiating these patents?

- HHS's top priority during the COVID-19 pandemic was establishing safe and effective medical countermeasures that would save lives and prevent human suffering from COVID-19.
- This strategy included leveraging a preexisting partnership with Moderna and the NIAID Vaccine Research Center (VRC) that had been established for the development of mRNA-based vaccine candidates against selected pathogens, including the coronavirus that causes Middle East respiratory syndrome (MERS).
- This partnership resulted in the development of an investigational vaccine against MERS.
- At the time of negotiations, it was unclear whether mRNA-based vaccines would be successful, NIH priorities were in line with what NIH has expertise in, the science –

ensuring the vaccine worked and those results were reliable, therefore NIH negotiated according to the science and the pressing public health need that:

- A single IRB would be used for all trials, to ensure rapid and consistent research
- Similar endpoints across trials, to facilitate comparison of trial results.
- Access to data that allowed evaluation of those endpoints.

Q: If the price is very high, doesn't that mean it fails to meet "practical application" in the statute?

- NIH shares concerns about high drug prices and the burden they place on patients and their families, particularly the uninsured and the underinsured. NIH and HHS are pursuing a whole of government approach informed by public input to develop a framework for implementation of the march-in provision. This framework will clearly articulate the guiding criteria and processes for making determinations, including where pricing is a factor and how "practical application" is assessed in these determinations.
- Practical Application, as defined in the statute refers to the manufacturer in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.
 - *Criteria 1.* Action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

Q: Has a march-in petition ever been granted by NIH?

- To date, no federal agency has exercised its march-in rights. NIH has considered the use of march-in on several occasions. For example, in the case of CellPro, two competing companies were in a conflict over the right to advance a cell therapy, and there was a government-funded patent involved in that dispute. NIH worked with the relevant parties to reach an agreement that addressed the specific issue raised. And in the case of Fabrazyme, a manufacturer experienced critical difficulties and was unable to produce enough drug to supply patients with full doses of a product to treat a rare disease. NIH and FDA worked with the company until the matter was resolved. In both cases, NIH was able to work with the company to resolve the issue, and march-in was ultimately not needed.

Q: Has NIH received any prior march-in petitions for Xtandi?

- Similar petitions were submitted to NIH and the Army in 2016, requesting the use of march-in for Xtandi based on price. NIH and the Army each declined to exercise march-in authority as Xtandi was found to be widely available to the public in the marketplace.

Q: What did NIH fund in the development of Xtandi?

- NIH and the U.S. Army are cited as the sources of funding in three inventions utilized by Astellas Pharma, Inc. for manufacturing Xtandi (enzalutamide). This NIH funding (NIH

Grant 5P50CA092131) supported University of California researchers in their discovery of a new set of chemical compounds and their potential use in treating hormone refractory prostate cancer. These patents are under a license from the University of California, the patent owner.

Q: Why did it take over 12 months for NIH to come to this decision?

- NIH thoroughly reviewed the petition in a manner consistent with the policy and objectives of the Bayh-Dole Act, including an assessment of the relevant intellectual property and applicability of the four statutory criteria. This required time and careful consideration. During this time, NIH and HHS also launched a whole of government approach to develop a framework for implementation of the Bayh-Dole march-in provision.

Maternal Health Initiative

(Dollars in Millions)

Agency	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
AHRQ	--	7	+7
CDC	97	148	+51
HRSA	157	276	+119
IHS	7	10	+3
NIH ¹	30	30	--
Total	291	471	+180

1/ Does not include costs NIH would assume as one-time for Implementing a Maternal health and PRenancy Outcomes Vision for Everyone initiative.

TALKING POINTS:

- The FY 2024 budget includes \$471 million to continue HHS's longstanding efforts to **reduce maternal mortality and morbidity** rates; expand maternal health initiatives in rural communities; implement implicit bias training for healthcare providers; create pregnancy medical home demonstration projects; and address the highest rates of perinatal health disparities, including by supporting the perinatal health workforce.
- The U.S. has the **highest maternal mortality rate** among developed nations, with a higher proportion effecting Black and American Indian/Alaska Native women. HHS is working to **end these race-based disparities and address adverse maternal health outcomes** by supporting programs that address implicit biases, investing in innovative strategies to achieve equitable maternal care, establishing a diverse workforce, and ensuring federal funded activities focus on equal treatment, inclusion, and accessibility.
- HHS's maternal health initiatives **addresses this significant public health problem**. Investments focus on four strategic goals: 1) healthy outcomes for all woman of reproductive age, 2) healthy pregnancies and births, 3) optimizing postpartum health; and 4) improving data and bolstering research.

QUESTIONS:

Q: What investments have HHS made in the last fiscal year to address the nation's overall maternal health?

- HHS approved the extension of Medicaid and Children's Health Insurance Program (CHIP) coverage for 12 months after pregnancy. An estimated 333,000 Americans annually in 23 states and D.C. are now eligible for 12 months of postpartum coverage. If all states adopted this option, as many as 720,000 people across the United States annually would be guaranteed Medicaid and CHIP coverage for 12 months after pregnancy.
- HHS also invested investing \$8.5 million in initiatives designed to reduce pregnancy-related deaths and complications that disproportionately impact minority populations and those living in rural areas.

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- HHS also awarded \$337 million to 56 states, territories, and nonprofit organizations through its Maternal, Infant, and Early Childhood Home Visiting Program to support communities and provide voluntary, evidence-based home visiting services to women during pregnancy, and to parents with young children up to kindergarten entry.

Program Information

The budget increases investments for the Maternal Health Initiative in the United States with increases across HHS totaling +\$471 million including:

- AHRQ: +\$7 million above FY 2023 enacted for a total of \$7 million to ensure that Federal, State, and local policymakers have timely and accurate data and useful analytic resources about maternal morbidity and mortality and the healthcare system with which to make informed policy decisions.
- CDC: +\$51 million above FY 2023 enacted, for a total of \$148 million, to provide additional funding to all states and territories for Maternal Mortality Review Committees, with a focus on promoting representative community engagement, and to increase support for tribes.
 - Additional funding will also be directed to 1) expand Perinatal Quality Collaboratives to every state, 2) increase support for the Pregnancy Risk Assessment Monitoring System, 3) support tools to help states develop coordinated regional systems to help those at high risk of complications receive care at a birth facility that is best prepared to meet their health needs.
- HRSA: +\$119 million above FY 2023 enacted, for a total of \$276 million to support maternal health activities across HRSA including:
 - Special Projects of Regional and National Significance: +\$80 million above FY 2023, for a total of \$80 million to support investments for community-based organizations to addressing social determinants of maternal health and to diversifying the doula workforce.
 - Training for Health Care Providers: +\$5 million above FY 2023, for a total of \$5 million, to fund up to 10 grants to train health care providers on implicit bias with the goal of reducing racial disparities.
 - Pregnancy Medical Home Demonstration: +\$15 million above FY 2023, for a total of \$25 million, to continue support for up to 12 awards for projects to foster the development and demonstration of innovative models that integrate care and services that reduce adverse maternal health outcomes and maternal deaths.
 - Rural Maternity and Obstetrics Management Strategies: +\$2 million above FY 2022, for a total of \$10 million, to expand maternal and obstetrics care in rural communities.
 - Growing & Diversifying the Nursing Workforce: +\$17 million above FY 2022, for a total of \$25 million, to grow and diversify the maternal and perinatal health nursing workforce by increasing and diversifying the number of Certified Nurse Midwives with a focus on practitioners working in rural and underserved communities.
- IHS: +\$3 million above FY 2023 enacted, for a total of \$10 million to expand efforts to provide culturally sensitive maternity care to pregnant and postpartum women, including efforts to treat pregnant and postpartum women with substance use disorder. Additional FY 2024 funding will support additional maternal case managers in IHS and Tribal Health Programs and to expand access to evidence-based training for health professionals across the IHS system.

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- NIH¹: \$30 million, flat with FY 2023 enacted, to continue support for the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative, an evidence-based approach to reduce preventable maternal deaths and associated health disparities for women at all stages of pregnancy.

BACKGROUND:

- The budget also includes other non-initiative maternal health funding across several agencies in HHS.
- Despite medical care advances and increased access to care, in 2020, there were 861 maternal deaths in the United States, representing a maternal mortality rate of 23.8 per 100,000 live births, which is an increase from the 17.4 deaths per 100,000 live births in 2018.
- Although most pregnancy related deaths are preventable, racial, and ethnic disparities in pregnancy-related deaths have persisted over time. According to the CDC, Black and American Indian/ Alaska Native (AI/AN) women are two to three times more likely to die from pregnancy-related causes than white women – and this disparity increases with age.
- A recent report with data from 13 state Maternal Mortality Review Committees determined that each pregnancy-related death was associated with several contributing factors, including access to appropriate and high-quality care, missed or delayed diagnoses, and lack of knowledge among patients and providers around warning signs. Their data suggest most deaths – 60% or more – could have been prevented by addressing these factors at multiple levels.

¹ The maternal health initiative crosscut also includes \$3 million, flat with FY 2023 enacted, for NIH to continue research on the effects of COVID-19 on pregnant and lactating individuals.

Medicare Coverage of Innovative Technology (MCIT) and Transitional Coverage for Emerging Technologies (TCET)

TALKING POINTS:

- HHS is committed to making sure people with Medicare are able to benefit from innovative, emerging technologies.
- HHS, through CMS, remains committed to establishing an expedited Medicare coverage pathway that achieves timely and predictable coverage of medical devices while at the same time ensuring that coverage is based on scientifically sound clinical evidence.
- HHS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections.

If asked about FDA/CMS authorities:

- The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) have different legal authorities to use when considering product authorization and coverage, respectively.
- The FDA makes marketing authorization decisions based on whether a product's safety and effectiveness while CMS makes coverage decisions based on something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- These two processes are separate and run independently by the two agencies.

QUESTIONS:

Q: Why did CMS repeal the January 2021 Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” (R&N) final rule?

- The January 2021 final rule established a coverage commitment for breakthrough devices without requiring demonstration of a health benefit in the Medicare population.
- Additionally, stakeholders were concerned that a codified definition of reasonable and necessary would remove existing flexibility and potentially impact the ability for CMS to ensure equitable health care access for all people with Medicare.
- We believe it is important to solicit additional feedback on this topic. We look forward to continuing to engage with a wide number of stakeholders as we determine appropriate next steps that are in the best interest of people with Medicare and the program overall.

Q: Didn't CMS stifle innovation and limit access to new technologies by repealing the January 2021 MCIT/R&N final rule? Why can't Medicare just cover what the FDA approves?

- The repeal of the January 2021 MCIT/R&N final rule does not mean an item or service is not covered. Devices may still be covered through claim-by-claim determinations, one or more local coverage determinations, or a national coverage determination. The standard

for Medicare coverage is not synonymous with the standards for FDA marketing authorization of devices, which are not specific to the Medicare population.

- FDA reviews a device to ensure it meets the applicable safety and effectiveness standard.
- Whereas evidence on whether or not a device is clinically beneficial to Medicare patients is a key factor in determining national coverage under Medicare.

Q: What has CMS done since the January 2021 MCIT/R&N final rule was repealed? Why is it taking so long for CMS to release the proposed TCET rule providing for a new expedited coverage pathway?

- CMS remains committed to establishing an expedited Medicare coverage pathway that achieves timely and predictable coverage of medical devices while at the same time ensuring that coverage is based on scientifically sound clinical evidence.
- CMS continues to work closely with patient groups, medical professionals and societies, medical device manufacturers, other federal agencies (including the FDA), and others involved in developing innovative medical devices as it moves policy forward.

Program Information

BACKGROUND:

Medicare Coverage of Innovative Technology (MCIT) and Transitional Coverage for Emerging Technologies (TCET):

- On January 14, 2021, CMS published the “Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” final rule, to be effective March 15, 2021.
- Before the rule was effective, CMS subsequently delayed the effective date until December 15, 2021. On September 15, 2021 CMS issued a proposed rule to repeal the MCIT/R&N final rule.
- On November 15, 2021 CMS published a final rule that fully repealed the MCIT/R&N final rule.
- Following the repeal, CMS held multiple listening sessions to receive feedback from stakeholders about which coverage process improvements would be most valuable.
- On October 12, 2022 in a JAMA Internal Medicine article, CMS discussed plans to initiate notice and comment rulemaking to explore policy options that would create an accelerated approval pathway. This pathway would build on prior initiatives, including coverage with evidence development. A proposed rule for Transitional Coverage for Emerging Technologies (TCET) was listed in the Fall 2021 Unified Agenda with a target publication date of October 2022. **INTERNAL -- we are now doing a procedural notice instead of a proposed rule. We have not made any public announcement yet.**

MA Prior Authorization Rules

Talking Points:

- In December 2022, CMS issued the Advancing Interoperability and Improving Prior Authorization Processes proposed rule that would modernize the health care system by requiring certain payers—including Medicare Advantage organizations—to implement an electronic prior authorization process, shorten the time frames for certain payers to respond to prior authorization requests, and establish policies to make the prior authorization process more efficient and transparent.
- The proposed rule would address challenges with the prior authorization process faced by providers and patients.

Questions:

Q: regarding support for Improving Seniors' Timely Access to Care Act (or generalized for other prior auth legislation)

- In December 2022, CMS issued proposed rules that would streamline prior authorization processes and improve prior authorization in Medicare Advantage to help Medicare Advantage enrollees have timely access to medically necessary care.
- We are grateful for your leadership on this important issue, including your work on the Improving Seniors' Timely Access to Care Act, and look forward to continuing to work with you and with Congress to make the prior authorization process more efficient and transparent in Medicare Advantage. HHS always appreciates the opportunity to provide technical assistance to Congress on important health care issues.

Program Information

Background

- Certain payers would be required to build and maintain an application programming interface, or API, that would automate the process for providers to determine whether a prior authorization is required, identify prior authorization information and documentation requirements, and facilitate the exchange of prior authorization requests and decisions.
- Certain payers would be required to send decisions within 72 hours for urgent requests and seven calendar days for standard, non-urgent requests, which is twice as fast as the existing Medicare Advantage response time limit for standard requests.
- Proposals also include requiring certain payers to include a specific reason when they deny a prior authorization request and to publicly report certain prior authorization metrics.
- In December 2022, CMS also issued the Contract Year 2024 Medicare Advantage and Part D proposed rule with proposed prior authorization policies that complement the policies from the Interoperability proposed rule.
- The rule proposes clarifications and revisions to regulations governing when and how Medicare Advantage plans develop and use coverage criteria and utilization management policies to ensure Medicare Advantage enrollees receive the same access to medically necessary care they would receive in Traditional Medicare.
- This rule also proposes policies to streamline prior authorization requirements and reduce disruption for Medicare Advantage enrollees.

Medicaid Disproportionate Share Hospital (DSH) Proposed Rule

- In February 2023, CMS issued a proposed rule that would implement statutory changes made by the Consolidated Appropriations Act of 2021 to update the methodology for the calculation of the hospital-specific DSH limit.
 - The law modified the calculation of the Medicaid portion of the hospital-specific DSH limit to include only costs and payments for services furnished to beneficiaries for whom Medicaid is the primary payer for such services. Accordingly, the limit excludes costs and payments for services provided to Medicaid beneficiaries with other sources of coverage, including Medicare and commercial insurance.
- Additionally, the proposed rule would enhance administrative efficiency by making technical changes and clarifications to the DSH program.
- CMS is seeking public feedback on this proposal and will closely review the comments they receive as they move forward with the decision-making process.

Medicaid Health Taxes Guidance

TALKING POINTS:

- In February 2023, CMS issued an informational bulletin reiterating federal requirements concerning health care-related taxes and hold harmless arrangements involving the redistribution of Medicaid payments.
- HHS recognizes that health care-related taxes often finance critical programs that pay for care provided to Medicaid beneficiaries and shore up the health care safety net.
- HHS will continue to approve permissible health care-related taxes that meet federal requirements and remains committed to working with states.

Program Information

Background: CMS issued the guidance after being approached by several states with questions regarding the statutory and regulatory requirements applicable to health care-related taxes, including in connection with proposals to implement or renew Medicaid managed care state directed payments (SDPs). Many of these questions have focused on whether health care-related tax arrangements involving the redistribution of Medicaid payments among providers subject to the tax comply with the statutory and regulatory prohibition on hold harmless arrangements. The informational bulletin reminds states of existing federal statutory and regulatory requirements and assists states in ensuring appropriate sources for the nonfederal share of financing, which is critical to protecting Medicaid's sustainability through responsible stewardship.

Medicare HI Trust Fund

TALKING POINTS:

- The FY 2024 legislative proposed law package strengthens the Medicare Trust Fund for a generation, without cutting benefits.
- The President's budget puts the Medicare Trust Fund in the strongest position it's been in for over two decades.²
- We achieve this by:
 - Directing all revenues from the net investment income tax, including tax code reforms that ensure high-income earners pay their fair share into the Medicare Hospital Insurance (HI) Trust Fund.
 - Crediting savings from prescription drug reforms to the HI Trust Fund.

QUESTIONS:

Q: How much of this plan is just general revenue transfers/gimmicks?

- This plan strengthens Medicare by ensuring that revenues going into the HI Trust Fund are sufficient to cover benefits. We achieve that by asking high-income people to pay a little more, achieving savings to Medicare from lowering the cost of drugs, without cutting benefits, and putting revenue that should have always gone to Medicare back where it belongs. Nothing about this proposal is a gimmick.
- The President fundamentally disagrees with those who believe that a conversation about Medicare should be a conversation about cutting benefits to seniors. His Budget shows that we can improve solvency while reducing seniors' costs – unless Congress takes revenues and prescription drug reforms off the table.
- *If pressed on general revenue transfers specifically:* The revenue from the Net Investment Income Tax was always intended to help strengthen Medicare. Fulfilling that purpose is both appropriate and important. Moreover, the large majority of the savings in this proposal come from new revenues and new prescription drug savings.

Q: Does your Budget double count the Medicare solvency provisions?

The Budget appropriately and transparently accounts for the impact on both the unified Budget and the Trust Funds, in exactly the way that the Congressional Budget Office and all other scorekeepers do.

Q: Are the tax proposals consistent with the President's \$400,000 pledge?

Yes. Nothing in the President's Budget raises taxes on people making less than \$400,000.

Q: Is this an opening bid for a real negotiation with Republicans over Medicare solvency as part of debt limit discussions?

² The [2002 Medicare Trustees Report](#) projected Medicare solvency extension of 28 years.

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- First, let me reiterate the President's stance on the debt limit: the full faith and credit of the United States is not up for negotiation, and Congress needs to do its job and increase the debt limit without conditions.
- The President is including a plan to strengthen Medicare in his Budget because it's part of his vision for the nation's economic and fiscal future.
- He welcomes a conversation with congressional Republicans about their competing vision, and that's why he's urged them to put forward their own budget, which is a necessary step to having that conversation.
- But I'd also note that the President has been clear about some things he won't agree to, including cutting Medicare benefits or taking away people's health care.
- The President looks forward to working with Congress to continue to strengthen Medicare's finances and reduce the cost of drugs for seniors.

Q: When was the last time a President proposed strengthening the Trust Fund for over 25 years?

- The FY 2000 President's budget proposed general fund transfers to support Medicare for over 25 years. A few years later, the Medicare actuaries projected 28 years of Medicare solvency under current law.

Program Information

BACKGROUND:

Current Law

Part A Trust Fund Deficit Under Current Law:

- The 2022 Medicare Trustees Report estimates insolvency in 2028.
- The FY 2024 President's Budget estimates insolvency in FY 2032. This difference from the Trustee's Report will not be obvious in public facing documents.
- Under current law, Part A Trust Fund spending exceeds dedicated revenues starting in CY 2026 and continuing indefinitely.
- The CMS actuaries project a **Trust Fund deficit of -\$222 billion over the 10-year period ending 2033.**
- See Chart 1 below illustrating Trust Fund balance changes under current law.

Proposed Law

The budget extends the life of Medicare by:

- Modestly increasing the Medicare tax rate on income above \$400,000.
 - The Budget proposes to increase the Medicare tax rate on earned and unearned income above \$400,000 from 3.8 percent to 5 percent.
 - Since Medicare was passed, income and wealth inequality in the United States have increased dramatically. By asking those with the highest incomes to contribute modestly more, we can keep the Medicare program strong for decades to come.
- Closing loopholes in existing Medicare taxes and dedicating the Medicare net investment income tax to the HI Trust Fund.
 - High-income people are supposed to pay a 3.8 percent Medicare tax on all of their income, but some high-paid professionals and other wealthy business owners have managed to shield some of their income from taxation by claiming it is neither earned income nor investment income.
 - The Budget would ensure that Medicare taxes apply to incomes over \$400,000 per year, without loopholes. It would also dedicate the revenue from the Medicare net investment income tax to the HI Trust Fund, as originally intended.
- Crediting savings from prescription drug reforms to the HI Trust Fund.
 - Building on the Inflation Reduction Act (IRA), the Budget strengthens newly established negotiation power by allowing Medicare to negotiate prices for more drugs and bringing drugs into negotiation sooner after they launch. It also strengthens the IRA requirement that drug companies pay rebates to Medicare when they increase prices faster than inflation by extending this rule to commercial health insurance.
 - The Budget credits the savings from these additional prescription drug reforms, amounting to \$200 billion over 10 years, to the HI Trust Fund.
 - Beneficiary premiums and the General Treasury finance Medicare Part B and D. Therefore, savings from strengthened prescription drug negotiation in the budget do not improve Medicare HI Trust Fund solvency unless specifically credited to the HI account.

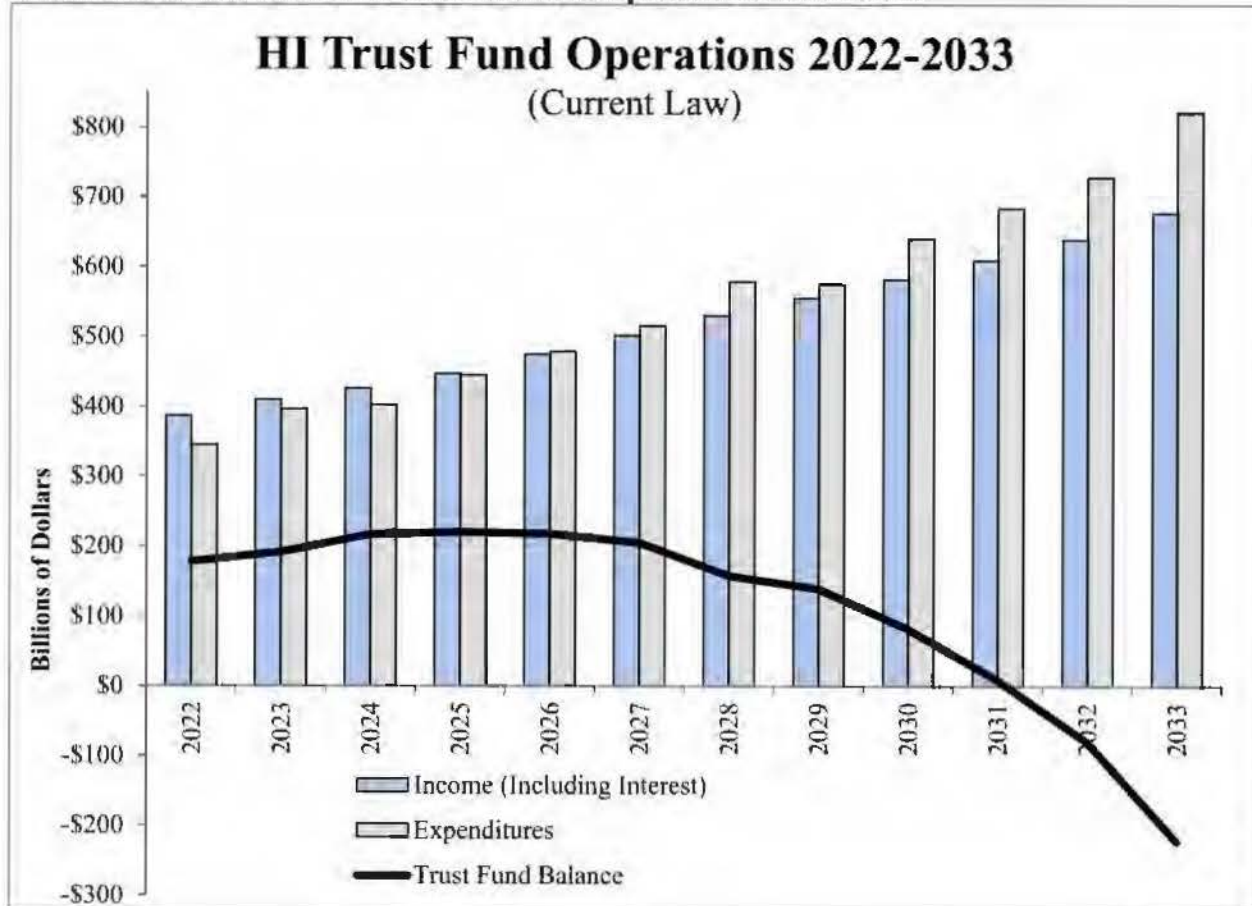
Solvency 101

- Medicare solvency is measured by the level of assets in the HI Trust Fund. In years when annual income to the Trust Fund exceeds benefits spending, the asset level increases, and when annual spending exceeds income, the asset level decreases.
- If the HI trust fund is not able to pay all current expenses out of current income and accumulated trust fund assets, it is considered to be insolvent.
- The reason we measure solvency of the HI trust fund is because the level of funding for the SMI Trust Fund (which covers Parts B and D) automatically updates each year to cover expenditures in the upcoming year. If actual costs exceed those estimated when the funding was set, the amount of financing in the next year (i.e., general revenues and beneficiary premiums) may be adjusted to recover the shortfall. Similarly, if actual costs are less than expected in a given year, income levels needed for the next year may be adjusted downward. Because of these automatic adjustments, the SMI trust fund is always kept in balance and cannot become insolvent.³
- Although some describe the HI Trust Fund as heading toward “bankruptcy” or “going broke”, the Medicare program will not cease to operate if assets are fully depleted.
 - Revenue will continue flowing into the fund from payroll taxes and other sources.
- Under current law, the Part A Trust Fund's reserves will become depleted in 2032 and revenues will be sufficient to pay 90 percent of total scheduled benefits.
- There is no statutory, automatic process, or precedent to determine how to apportion the available funds or how to fill the shortfall. But the Social Security Act does not authorize the federal government to use general revenues to fund the deficit. Therefore, Medicare will only be able to make payments according to funds available on a rolling basis through tax revenue.
 - How Medicare would pay claims for services is unknown. Two scenarios are possible:
 1. CMS would pay claims in full as tax revenue comes into the HI account. But because revenues come in slower than providers request payments, a backlog of claims would grow and the time between billing and payment will constantly increase. The effect will be providers getting paid the full amount they are due but waiting significant periods for their payments.
 2. CMS would pay a decreased rate for all claims. In 2032, instead of paying 100% of the claim, CMS would pay 90% of the claim in accordance with the asset ratio of the fund. The effect will be providers getting paid on time but less than the full amount.

³ Kaiser Family Foundation and supplemented by OGC.

Appendix – Graphs

Chart 1: Current Law Part A Trust Fund Expenditures vs. Income



Background

CMS Actuaries' memo posted to CMS website on 3/15/2023, which includes the below information:

- The Budget's total additional revenue dedicated to the HI trust fund from FY 2024 through FY 2033 is estimated to be \$1.4 trillion.
- The HI program can be directly modeled for a 25-year period by extending the President's Budget assumptions through that period.
- In the 25th year of the modeling, the HI Trust Fund balance is positive and growing; accordingly, the actual impact of the additional revenue may extend the Trust Fund depletion date by significantly more than 25 years.

Non-public – do not share/cite outside of HHS—For Internal Review Only
Transfers to HI Trust Fund (by source, dollars in billions)

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	<u>2024- 2033</u>
Current Law NIIT	22	37	38	39	40	42	44	47	50	52	55	444
Close NIIT loophole (NIIT/SECA rationalization)	13	23	25	27	28	30	31	33	34	35	36	303
Increase NIIT and HI Rate by 1.2% pt. above \$400k	17	36	36	39	41	43	46	49	52	55	58	453
<i>Subtotal NIIT and Increased Payroll Tax rates</i>	52	95	99	104	109	116	122	128	135	142	149	1,200
Drug Savings			1	6	13	25	25	30	31	32	37	200
Total	52	95	100	110	122	141	147	158	166	174	186	1,400

Medicaid - Unwinding

TALKING POINTS:

- HHS has been working with all states for well over a year to prepare for the unwinding of the continuous enrollment condition, in order to ensure that as many people as possible maintain a source of coverage during this "unwinding" period.
- We are working closely with states to help ensure that people have continuity of coverage and established a Marketplace Special Enrollment Period from March 31, 2023 through July 31, 2024 for consumers who are no longer eligible for Medicaid or CHIP due to the end of the continuous enrollment condition.
- CMS also is helping states build on the progress made by continuous enrollment during the pandemic by implementing continuous coverage for kids nationwide. Thanks to the omnibus, beginning next year, children in Medicaid and CHIP will receive continuous enrollment for a full year.

QUESTIONS:

Q: What barriers have you seen that will prevent people from easily enrolling in their state? For example, I heard that South Carolina has paper-only re-enrollment and doesn't allow any electronic re-enrollment.

- CMS is working closely with states on their unwinding plans, including assessing state compliance with federal Medicaid redetermination requirements and, where necessary, developing mitigation strategies to address gaps/deficiencies.

Q: What are you doing to ensure that individuals are able to retain access to health coverage during unwinding?

- HHS has been collaborating closely with state agencies, other federal agencies, and stakeholders to plan and prepare for the end of the continuous enrollment condition through regular workgroups, all-state calls, and individualized technical assistance. These efforts are aimed at ensuring eligible enrollees retain coverage by renewing their Medicaid or CHIP coverage, and enrollees eligible for other sources of coverage smoothly transition.
- CMS has announced a Marketplace Special Enrollment Period (SEP) for qualified individuals and their families who lose Medicaid or CHIP coverage due to the end of the continuous enrollment condition. In October 2022, CMS also issued final rulemaking to establish a Medicare SEP to Coordinate with Termination of Medicaid Coverage, which allows individuals who have missed a Medicare enrollment period to enroll in Medicare after termination of Medicaid eligibility.

Q: How many people do you expect to lose Medicaid coverage this Spring and Summer?

- States will have up to 12 months to initiate, and 14 months to complete, a renewal for all individuals enrolled in Medicaid. CMS is working closely with states on their unwinding plans, and CMS will be monitoring monthly data about activities related to eligibility

determinations and redeterminations conducted during the unwinding period, including data related to terminations of coverage and transitions to other sources of coverage. CMS will be reviewing this data, state activity, and other information to ensure all states comply with federal requirements related to eligibility redeterminations and renewals, and is committed to providing additional information once available.

- o **IF PRESSED:** According to estimates from the Office of the Assistant Secretary for Planning and Evaluation, 15 million people could be disenrolled from Medicaid during this time period, and 8 million of those individuals will be eligible for other health coverage.

Q: HHS ASPE projects that 15 million individuals will lose Medicaid coverage, and other studies estimate 16 million. What is the difference between these projections and the projections in the Budget?

- CMS Actuaries project that 16.9 million individuals will lose Medicaid coverage in FY 2024 as a result of the ending continuous enrollment condition, and 19.5 million will lose coverage over the course of the unwinding period. Some reasons for the differences between the actuary projections and other studies include:
 - o CMS actuaries follow a timeframe of the fiscal year for purposes of the President's Budget
 - o CMS actuaries do not account for churning, beneficiaries going on and off of coverage, in their projections they develop for budget purposes
 - o CMS actuaries uses data from the Transformed Medicaid Statistical Information System (T-MSIS). Other studies may use different data sources with different metrics that could lead to variances in projections.

Q: Will the special enrollment period be available in all states, even the ones that don't rely on HealthCare.gov for their Marketplace?

- State-Based Marketplaces that operate their own eligibility and enrollment platforms can offer this SEP for their populations, and HHS encourages them to do so.

Q: Why aren't you requiring all states to offer the special enrollment period?

- State-Based Marketplaces that operate their own eligibility and enrollment platforms must determine whether to offer this SEP for their populations, and HHS encourages them to do so.

Q: Will Medicaid still be required to cover COVID-19 vaccines, testing, and treatment?

- If the COVID-19 PHE ends as expected on May 11, 2023, this COVID-19-specific coverage requirement will end on September 30, 2024. Under the American Rescue Plan Act of 2021 (ARP), states must provide COVID-19 vaccinations, testing, and treatments under Medicaid and CHIP without cost sharing for through the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE.

Internal Use Only – U.S. Department of Health and Human Services

- Even after the ARP provision expires, most people enrolled in Medicaid or CHIP will be guaranteed coverage of all approved vaccines, including COVID-19 vaccines, recommended by the Advisory Committee on Immunization Practices. That is because the Inflation Reduction Act closes gaps in vaccine coverage for adults in Medicaid and CHIP effective October 1, 2023. Medicaid and CHIP coverage of COVID-19 treatments and testing may vary by state.

Medicare Advantage

TALKING POINTS:

- Our vision for Medicare is for all seniors and people with disabilities to receive equitable, high quality, and person-centered care that is affordable and sustainable. This applies to beneficiaries in traditional Medicare and in Medicare Advantage.
- We recognize that Medicare Advantage is important for many beneficiaries. That's why we issued a Request for Information (RFI) last year seeking input on how to improve the MA program.
- Using this feedback, across multiple rules and the Advance Notice, we have proposed policies to strengthen beneficiary protections and enhance the MA program, including improvements that enhance payment accuracy.

QUESTIONS:

Medicare Advantage Advance Notice

Q: Is the MA Advance Notice actually a cut to Medicare and MA plan payments?

- Any claim that this Administration is cutting Medicare is categorically false.
- This Administration has proposed a roughly \$4 billion increase in MA payments for next year.

Q: What will the impact be on dually-eligible beneficiaries, lower-income enrollees, and racial or ethnic minorities?

- Bottom line, we are not proposing any policies that harm vulnerable beneficiaries.
- CMS is proposing essential updates to the risk adjustment model, including updates to reflect more recent cost and utilization data and to incorporate ICD-10 codes. These updates improve payment accuracy.
- We will continue to pay much more for someone who is dually eligible than someone who isn't even when they have the same diagnoses, and Federal law protects most dually eligible individuals from any cost sharing for Medicare services.
- The Medicare Advantage market is strong, and nothing in the Administration's proposed policies will change that.

Q: Will MA plans reduce the benefits they offer or increase premiums because of the Advance Notice?

- To be clear, on average, the Advance Notice would provide a payment increase for MA plans of 1.03%, or more than \$4 billion, next year.
- Also, all core Medicare benefits – such as hospital care and physician visits – are guaranteed in Medicare Advantage like they are in Traditional Medicare. These changes do not impact that requirement.

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- Looking at the past is helpful here. There have been years when the MA increase was smaller than what is proposed for 2024. We did not see premiums increase over those years. Instead, premiums remained relatively stable.
- MA is a highly competitive market where plans often compete for enrollees by keeping premiums down. In this competitive environment, we expect premiums to remain low.

Mental Health Parity

TALKING POINTS:

- The President's FY 2024 Budget includes numerous proposals to improve patient protections and strengthen enforcement of mental health parity requirements, including:
 - o Funding to states for parity enforcement;
 - o Eliminating Medicare's 190-day lifetime limit on psychiatric hospital services;
 - o Subjecting more plans – including Medicare Advantage plans – to parity laws; and
 - o Authorizing the Secretaries of HHS, Labor, and Treasury to regulate behavioral health network adequacy, and to issue regulations on a standard for parity in payment rates.
- The budget includes a proposal requiring Medicare and private insurance to cover up to three behavioral health visits per year with no cost-sharing. Eliminating cost-sharing for individuals removes potential financial barriers to treatment and gives more patients access to the care they need.
- The budget also includes a proposal to allow Medicare to identify and designate additional professionals to provide behavioral health care services, expanding access particularly in rural and underserved areas.

QUESTIONS:

Q: What does HHS do to enforce mental health parity requirements? Do you audit plans?

- HHS has primary enforcement authority over issuers in states that do not have authority to enforce or fail to substantially enforce the Mental Health Parity and Additional Equity Act (MHPAEA) (referred to as direct enforcement states) and non-Federal governmental health plans in all states.
- CMS is tasked with carrying out HHS's enforcement responsibilities.
- While CMS has some enforcement authority, states are the primary enforcers of mental health parity for health insurance issuers. The President's FY 2024 Budget includes a proposal that would grant states an additional \$125 million in funding for enforcement activities.

Q: Congress just added marriage and family therapist services to the Medicare statute, why are additional changes needed to Medicare?

- There are current statutory limits on the types of practitioners, and the scope of services, that are eligible for Medicare payment and these limits restrict access to behavioral health services.
- The Consolidated Appropriations Act of 2023 added coverage of marriage and family therapist services and mental health counselor services under Part B of the Medicare program starting January 1, 2024.
- However, other providers including peer support workers and certified addiction counselors are still unable to bill Medicare directly.
- The Budget proposes to allow Medicare to identify and designate additional professionals who can enroll in Medicare and be paid when furnishing behavioral health services within their applicable state licensure or scope of practice that would otherwise be covered when furnished by a physician.

Internal Use Only – U.S. Department of Health and Human Services

- The proposal also:
 - o Removes limits on the scope of services for which Clinical Social Workers can be paid by Medicare.
 - o Establishes a Medicare benefit category for these professionals that authorizes direct billing and payment under Medicare for these practitioners;
 - o Removes limits on the scope of services for which they can be paid by Medicare;
 - o Allows these practitioners to bill Medicare directly for their mental health services for covered Part A qualifying Skilled Nursing Facility stays;
 - o Establishes Medicare payment under Part B for services provided under an Assertive Community Treatment delivery system which provides treatment for the severe functional impairments associated with serious mental illness;
 - o Allows payment to Rural Health Clinics and Federally Qualified Health Centers for these additional behavioral health professionals providing mental health services; and
 - o Enables Medicare coverage of evidence-based digital applications and platforms that facilitate the delivery of mental health services.

Mental Health - Youth

TALKING POINTS:

- Children and young people in this country are facing an unprecedented behavioral health crisis
- Diagnosis of anxiety, depression, and other mental health conditions, as well as the rate of youth overdose deaths continue to rise at alarming rates.
- Improving mental health and wellness for everyone -- particularly for children and young people—and addressing the challenges that have been exacerbated by the COVID-19 pandemic is a top priority for HHS.

QUESTIONS:

Q: How has the COVID-19 pandemic and mask wearing impacted children’s mental health and what is HHS doing about it?

- Data show that for across a broad range of social, emotional, and cognitive outcomes, allowing kids to attend school in person is incredibly important.
- Accordingly, the Biden Administration has prioritized in-person schooling in its COVID response plan.
- HHS is responding to the current crisis by developing and expanding grant programs that address the mental health needs of our children and youth, including school-based programs and community-based trauma-informed services for children and youth, and their families that meet children and families where they are.

Q: A few months ago, HHS/SAMHSA released the results of its annual National Survey on Drug Use and Health. In 2021 amount people 12 and older, 61.2 million people, 21.9 percent of the US population, used illicit drugs this past year. 3.7 million, 14.1 percent of 12- to 17-year-olds have used illicit drug. These are children and substance use among America’s kids only seem be increasing. Why should we continue providing SAMHSA additional dollars when it is clear what you are doing is not making a positive impact?

There is no question that more needs to be done, and with support from Congress we are taking action, expanding grant programs that address the mental health needs of our children and youth, including school-based programs and community-based trauma-informed services for children and youth, and their families that meet children and families where they are.

If pressed on the specifics of the data and year-over-year increase:

- To clarify, estimates from the 2021 National Survey on Drug Use and Health should not be compared with estimates from previous years because the COVID-19 pandemic necessitated methodological changes to the data collection process.

Internal Use Only – U.S. Department of Health and Human Services

- HHS is committed to providing access to prevention and treatment services to everyone, include youth and young adults, and a commitment to data and evidence is one of SAMHSA's four core principles.
- The National Survey on Drug Use and Health is a vital data tool that supports SAMHSA's mission and aligns with SAMHSA's vision to guide stakeholders in developing policies and programs to help people in the United States who have, are affected by, or are at risk for mental health or substance use conditions receive care, thrive, and achieve wellbeing.

Q: Please give an example of how HHS agencies are coordinating to address youth mental health and substance use disorder conditions?

- When I was confirmed, I immediately established the Behavioral Health Coordinating Council (BHCC)—all HHS agencies participate and lead committees across five key areas: data and evaluation, youth, crisis and suicide, overdose prevention, and integration. Committees all consider equity and workforce as part of their charge.
- SAMHSA and CMS lead our BHCC youth group together. And they also work together through the Interdepartmental Serious Mental Illness Coordinating Committee, which was established to make recommendations for actions that federal departments can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance, has parity implementation as a goal.

Program Information

Suicide is one of the gravest public health problems impacting youth in the United States. It is the second leading cause of death for young people, and according to mortality data released by the CDC, the youth suicide rate in 2021 appears to be the highest rate on record.

For the past two years, the COVID-19 pandemic has negatively affected the lives of young people and has contributed to worsening mental health challenges in the country. The immediate consequences of the pandemic on mental health are further complicated by the association of longer-term consequences, such as “Long COVID.” However, the youth mental health crisis predates the pandemic and youth have experienced increased rates of suicidality, hopelessness, and sadness over the last decade.

Still, youth suicide is largely preventable. Implementing suicide prevention, intervention, and postvention strategies, through the Garrett Lee Smith (GLS) grants, has been shown to prevent suicide and suicide attempts. Previous rigorous evaluations have found that counties implementing GLS programming had lower suicide rates, and lower suicide attempt rates, up to two years following implementation of activities, compared to similar counties with no such programming. The GLS State/Tribal grant is available states and tribes to support youth suicide prevention activities, through a public health approach, for youth through 24 years old.

In 1992, SAMHSA created the Children’s Mental Health Initiative (CMHI) which provides “systems of care” (SOC) for children and youth with serious emotional disturbances (SED) and their families. SOC helps prepare children and youth for successful transition to adulthood and assumption of adult roles and responsibilities by delivering services in the least restrictive environment with evidence-supported treatments and interventions.

SAMHSA also established 988 last year, including standing up a nationwide text line with a 98 percent response rate—overwhelmingly, it is the modality that young people are using to reach to 988.

Mifepristone

TALKING POINTS:

- [ON HOLD UNTIL DECISION]
- Holding Statement if Decision Comes out During Hearing:
 - “This is chilling news for America and will have dire consequences for women across the country. The Biden-Harris Administration is resolute in our commitment to protect access to abortion care – we are looking closely at the decision and are examining our options.”

QUESTIONS:

Q: Does HHS have any workarounds to this decision?

- [ON HOLD UNTIL DECISION]

Q: What do providers/patients do with existing mifepristone?

- [ON HOLD UNTIL DECISION]

Q: If you feel that this decision was made erroneously, why don't you just defy the ruling?

- [ON HOLD UNTIL DECISION]

Q: Are you going to issue a Public Health Emergency to increase access to reproductive health care?

- We have always said we would not take any option off the table that will help expand access to reproductive care.
- But, at this point in time, we do not believe that declaring a public health emergency would provide meaningful new resources in this fight.

Nonrecurring Expenses Fund

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Notification	525	650	125
Rescission	(650)	(350)	300

TALKING POINTS:

- HHS relies on modern information technology and safe and functional facilities to meet its mission to enhance the health and well-being of Americans.
- The Nonrecurring Expenses Fund enables HHS to address high-priority capital investments that simply do not get funded in the annual appropriations process.
- Every dollar rescinded from the fund comes at the expense of keeping departmental systems and facilities in good working order.
- Approximately two-thirds of HHS' NEF-eligible needs are not even proposed to Congress due to these rescissions and allocations.

QUESTIONS:

Q: How much of the NEF has funded Capital Expenditures?

By statute all NEF investments must be capital expenditures necessary to operate the Department. Since its inception, HHS has obligated \$1.9 billion in facilities and \$2.7 billion in IT capital expenditures previously notified to Congress. HHS is currently in the process of spending the remaining \$1.3 billion in notified funds.

Program Information

- **Congressional Notification:**
 - The Department is required to notify Congress on planned uses of the Fund. As of FY 2023, approximately \$5.9 billion has been notified to the House and Senate Appropriations Committees from the NEF since FY 2013.
- **Historical Funding:**
 - Since FY 2013, the NEF has supported nearly \$3.2 billion in physical infrastructure projects and \$3.3 billion in IT infrastructure projects.¹
- **Congressional Rescissions:**
 - Since FY 2017, the Congress has enacted over \$3.7 billion in rescissions and directed allocations from the NEF which has diminished the potential value of the fund across the Department.
 - Approximately two-thirds of HHS' NEF-eligible needs are not even proposed to Congress due to these rescissions and allocations.
- **Recent Requests:**
 - HHS OpDivs and StaffDivs requested over \$2.3 billion in new capital expenses from the NEF across FY 2023 and 2024, many of which are to address the backlog of facility maintenance and repair needs. Only a fraction of these projects in addition to the critical IT projects can be addressed at the current rescission levels.
 - Since the beginning of NEF, OpDivs have been able to use NEF funding to minimize their Building Maintenance and Repair and IT infrastructure backlog and keep necessary operations going.
 - CDC has received \$685 million.
 - NIH has received \$940 billion for ongoing facilities maintenance and operations.
 - IHS has received \$1.0 billion for hospital expansions and renovations, including staffing quarters, IT systems to assist in the communication among health centers and upgrades to strengthen cybersecurity.

¹This sums to more than the \$5.9 billion notified since FY 2013, because this includes the FY 2024 amount (\$650M) that is included in the top table but has not yet been formally notified for. The notification process occurs late summer towards the end of the fiscal year.

Nursing Homes - Staffing Ratios

TALKING POINTS:

- One of the key areas of focus in President Biden’s nursing home quality initiative is nursing home staffing.
- The COVID-19 pandemic highlighted and exacerbated the long-standing staffing challenges experienced in many facilities, creating an urgent need to address this issue for the well-being of all individuals residing in our nation’s federally certified nursing homes, and the workers who care for them.
- HHS has launched a multi-faceted approach aimed at determining the minimum level and type of staffing needed to enable safe and quality care in nursing homes. As part of this effort:
 - o CMS is currently in the process of conducting a mixed methods study
 - o CMS will release a proposal in spring 2023 for minimum staffing levels in nursing homes.

QUESTIONS:

Q: How has the nationwide health care workforce shortage impacted rural providers that are already struggling?

- We know that providers across the country are still facing challenges introduced or exacerbated by the COVID-19 pandemic, including workforce shortages, and these challenges can be particularly difficult for providers in rural areas.
- Health care should be accessible, no matter where you live, and the Biden-Harris Administration is dedicated to improving access to health care in rural communities and addressing the issues which contribute to health inequities impacting these communities.
- Fewer nurses are working in rural areas today than in the past. HHS is investing \$387 million an increase of \$190 million for Behavioral Health Workforce Development Programs, which will support the training of 18,000 behavioral health providers and seek to place these providers in rural and underserved areas.

Q: Will your nurse staffing proposal include an exception or other flexibilities for rural nursing homes?

- We are aware of the unique challenges facing rural nursing homes and we are taking those challenges into account as we develop the proposal. We look forward to robust comment from the rural community on the proposal when it is released.

Q: The health care workforce shortage is reaching a crisis, yet the Administration still refuses to let healthy, qualified professionals work unless they’ve received an experimental vaccine that doesn’t even prevent COVID-19. Now that the Public Health

Emergency is coming to an end, don't you think it's time to get rid of the vaccine mandate as well?

- We know that the COVID-19 vaccine saves lives, and the Biden-Harris Administration has made it a priority to continually work to reach, vaccinate, and protect our most vulnerable communities across the country.
- Hospitalizations and deaths from COVID-19 currently remain relatively low nationwide. This is a testament to the tools and protections put in place by this Administration, including efforts to educate consumers and expand access to the vaccine.
- HHS is committed to taking critical steps to protect vulnerable individuals and ensure America's health care facilities are prepared to respond to public health emergencies.

Ohio Train Derailment

TALKING POINTS:

- HHS stands with the people and communities impacted back the train derailment in Norfolk Southern. Multiple parts of HHS are part of the federal response.
- In February, CDC/ATSDR sent a team of 23 staff to conduct an Assessment of Chemical Exposures (ACE) investigation, including door-to-door recruitment of affected residents.
- As of March 19, 2023, over 613 residents and 304 first responders have participated in the ACE survey.
 - The investigation is providing information to inform the states' public health response, assess the need to modify emergency response procedures, focus outreach efforts, and identify groups of exposed people that may need additional follow-up.
- The Health Resources and Services Administration (HRSA) has provided an emergency grant to the Community Action Agency of Columbiana County (CAAC). HRSA approved, \$250,000 in emergency funding. This funding will support key response activities, including direct health care services, patient screenings, and outreach and enrollment.
- HHS will continue to support the community throughout the next stages of the response whether that's through reviewing environmental sampling data to assess public health impact or to provide mental health support, we stand ready to assist.

QUESTIONS:

Q: Some residents and experts have stated a need for testing to measure the level of chemicals the residents and responders to the East Palestine incident were exposed to. Why hasn't CDC/ATSDR offered biomonitoring or other testing to residents?

- I understand that many residents and responders have concerns regarding the longer-term health outcomes resulting from the train derailment. HHS is committed to supporting the residents of East Palestine and the surrounding communities to address their concerns, including answering their questions about how testing may help them protect their health.
- At this time, CDC and ATSDR are not recommending specialized testing for the levels of chemicals in people's bodies, as tests for the chemicals involved in this event do not usually provide information to help doctors manage health problems or disease.
- We are supporting state efforts to connect concerned residents with medical providers to ensure they have access to follow-up care in the long-term to address any individual health issues that may arise.
- CDC and ATSDR are also working with partners to provide information to health care providers about additional steps they can take in consultation with their patients, including other routine blood and urine tests that they can take to protect their patients' health.

Q: When will you have ACE results? Will there be one report? Who will release the report/findings and how long will this take?

- The resident and responder surveys for the Assessment of Chemical Exposures, or ACE, investigation will be open through the end of the month, and data analysis is ongoing. Over the next several months, CDC and ATSDR will work together with the health departments to analyze data and share results.
- These results will provide information about appropriate next steps to address potential health impacts of exposures.
- This is a collaborative, iterative process and CDC/ATSDR will continue to work closely with the health departments as the analyses are completed and results are shared.

Q: Does the CDC recommend that we study these people over time to learn about the health effects?

- The health of the residents and the community overall is very important to us. I know that community members are concerned about their health and understand how unsettling it can be not to know what these exposures mean.
- We hope to learn more from the ACE survey in the community and among responders to give us more information to address the health concerns of the residents.
- We will analyze the data with our colleagues from the Ohio and Pennsylvania health departments and come up with a plan for next steps. This may include long-term health monitoring, additional epidemiologic support, or suggest research studies to fill knowledge gaps.

Q: How does ATSDR produce their screening levels for exposures (also called comparison values). How are these values used and why are these values different than the ones the EPA and health departments are using?

- ATSDR has been on the ground supporting the EPA and local officials in their response to the derailment for over a month. At the request of the EPA and state health departments, ATSDR provided comparison values to the EPA and state health departments for consideration in their risk management process.
- We defer to EPA and the state health departments for more information on how these comparison values are used in the risk management process.
- Determining the threshold for unsafe levels of chemical exposure is a complex process given there are many site-specific factors that need to be considered. ATSDR derives non-regulatory comparison values as screening values to help public health professionals determine which exposures may need further evaluation. ATSDR uses the lowest comparison value available to protect public health for a specific incident.
- Concentrations below these values are unlikely to cause harmful health effects. Exposures above these values do not necessarily mean that harmful effects will occur but serve as a signal for public health professionals to look more closely.

Older Americans Act

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Protection of Vulnerable Older Adults	96	144	+49
Health and Independence for Older Adults	1,587	1,939	+352
Caregiver Services	259	311	+49
Total Program Level	2,650	3,142	+493

TALKING POINTS:

- At some point in our lives, nearly all of us will need assistance with things like transportation, personal care, and managing finances, or provide assistance to someone else we care about. Strengthening and supporting the caregiving infrastructure is a top priority for this Department.
- ACL's budget request includes an increase of nearly \$66 million to support:
 - a range of services to support family caregivers including respite care,
 - efforts to implement recommendations from the National Strategy to Support Family Caregivers, and
 - demonstration grants and a technical assistance center to expand and stabilize the direct care workforce.
- The demand for services provided through the ACL's programs has risen sharply in recent years and continues to grow. Expanding access to these direct services is a priority.

QUESTIONS:

Q: Falls among older adults result in \$50 billion in medical costs annually – \$38B in Medicare and Medicaid; and \$12B in private insurance or out-of-pocket expenditures. What are you proposing to improve this situation?

- First, I wanted to thank Congress for your support of HHS falls prevention work. In particular, the \$5 million that was appropriated in FY 2023 for the Administration for Community Living's Research, Demonstration and Evaluation Center. Those funds are supporting continued research in the causes and associated illnesses that can lead to falls as well as interventions effective in preventing falls.
- As part of ACL's investment in direct services, we are requesting an additional \$2 million within our promoting healthy aging efforts to expand the successful evidence-based falls prevention program in the community and educate more older Americans about ways to reduce their falls risk.

Q: You have indicated that direct services for older adults and people with disabilities are a priority and nutrition services in particular. Why are you proposing to cut the Nutrition Services Incentive Program by \$48 million?

- I agree, funding to meet nutrition needs – whether at group dining sites like senior centers or through home-delivered meals – are critical to enabling seniors to remain in their communities and to age in place. The Nutrition Services Incentive Program is a secondary source of funding for the nutrition services.
- We have requested an overall increase to these programs through their primary funding, which comes to \$217.6 million over the FY 2023 budget. We believe increasing primary funding will have the most direct impact on addressing the nutrition needs of seniors.

Q: What does this budget do to address elder abuse and neglect?

- Abuse and neglect rob people of their fundamental human rights and erode their opportunity to participate as members of the community. We are in a national crisis – abuse of older adults increased nearly 84 percent during COVID.
- I thank Congress for providing the first federal funding for APS formula grants in FY 2021 and I am so pleased that ACL received ongoing funding to support Adult Protective Services in FY 2023.
- Our request for FY 2024 is to get to a basic level of funding to continue to protect older adults and adults with disabilities from abuse and neglect.

Organ Transplantation

(Dollars in Millions)

	FY 2023	FY 2024	
	Enacted	President's Budget	+/- FY 2023 Enacted
Organ Transplantation	31,049	67,049	+36,000

TALKING POINTS:

- We are committed to increasing the number of registered organ donors and initiatives to **remove financial barriers** to living organ donation and to ensure that donor allocation is done in a **transparent and equitable** manner.
- As you know, almost 40 years ago, Congress established the Organ Procurement and Transplantation Network (OPTN) to coordinate and operate the nation's organ procurement, allocation, and transplantation system.
- We are currently engaged in efforts to **modernize** the OPTN to further strengthen accessibility, equity, transparency, and system performance.
- We want to **work with Congress** to continue our efforts to improve organ transplantation. The President's Budget includes a proposal for the resources and authorities needed to oversee the operational activities, performance, and accountability of the OPTN.

QUESTIONS:

Q: How is HHS providing oversight to ensure accountability and equity of the Organ Transplantation and Procurement Network system?

- The Budget provides an additional \$37 million to increase accessibility, transparency, and equitable distribution of organs through modernization of the Organ Procurement and Transplantation Network.
- Specifically, the request will support efforts to:
 - strengthen policy, governance, and technology to drive improvements in IT system performance, health equity, patient outcomes and patient safety
 - launch implementation of the design features needed to improve system processes, patient experience, and accountability

Program Information

BACKGROUND:

- National Organ Transplantation Act (NOTA) specifies that the OPTN be operated under federal contract by a private, non-profit entity having expertise in organ procurement and transplantation.
- The law has not been updated in 40 years and there has only been one Organ Procurement and Transplantation Network contractor, the United Network for Organ Sharing (UNOS).
- The current OPTN contract is set to expire in September 2023. HHS issued a Request for Information in April 2022 to seek stakeholder feedback, and in response to the feedback, HHS, in coordination with U.S. Digital Service, is launching an OPTN Modernization Initiative.
- The OPTN Modernization Initiative will be a multi-year effort to strengthen accountability, equity, and performance of the organ donation, procurement, and transplantation system.
- HHS is building its capacity to support a modernized OPTN and will be engaging a Program Management Support contractor to assist in the modernization.
- In addition to the budget request, there are A-19s as part of the President's Budget. The requested statutory changes would help strengthen OPTN functions and improve outcomes for patients and families by enhancing HHS oversight, improving transparency of OPTN data and operations, and improving overall efficiency of the organ transplantation system. In addition, the changes would provide the flexibility to increase competition between the organ procurement organizations (OPOs) while minimizing disruption to organ procurement.

Oversight

TALKING POINTS:

- HHS is committed to working in good faith to address congressional oversight requests in a timely manner.
- Already this Congress, HHS has made significant document productions in response to multiple committees' oversight inquiries, and I know we are actively working to continue addressing Congress's oversight requests.
- We look forward to working together and continuing our productive relationships with Congress.

QUESTIONS:

Q: Will you provide complete responses to my oversight requests by the deadline requested?

- We are committed to engaging in good-faith negotiations to meet the informational needs of Congress while protecting the institutional interests of the executive branch.
- We will continue to engage in this process to address congressional oversight requests, like we always have.
- *If pressed on commitments:* I know our staff is working hard to address the significant number of oversight requests that we have received this Congress. We look forward to continuing those discussions.

Q: Is it your policy that Committee Chairs must send new oversight letters this Congress to get answers to letters we sent in the last Congress?

- It is my understanding that, when a new Congress begins, there is a long-standing practice across Departments for oversight requests to be sent by the new Chairs, once they have been selected.
- This helps ensure we are prioritizing oversight requests from current committee Chairs.
- The Department welcomes current Chairs to send oversight letters identifying their priorities for this Congress and stands ready to work in good faith to address these requests.

Pandemic Preparedness

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA	153.113	181.880	+28.767
CDC ¹	1,654.300	2,037.400	+383.100
NIH ²	2,943.000	2,944.000	+1.000
ACF	1.864	8.000	+6.136
ASPR ³	3,629.677	4,271.913	+642.236
PHSSEF ³	115.992	278.318	+162.326
Pandemic Preparedness Initiative	--	20,000	+20,000
Total Program Level	8,497.946	29,721.511	+21,223.565

1/ FY 2023 totals are comparably adjusted to reflect funds for HHS Protect within CDC's Center for Preparedness and Response. The FY 2023 enacted located HHS Protect Funding within PHSSEF, but the program is implemented by CDC.

2/ NIH estimates for FY 2023 and FY 2024 align to the NIH Biodefense category.

3/ The Public Health and Social Services Fund previously contained the annual appropriation for the Administration for Strategic Preparedness and Response (ASPR). The FY 2024 budget requests funding for ASPR in a separate, new appropriation account. This table is comparably adjusted to break out ASPR from the PHSSEF.

TALKING POINTS:

- Strengthening our nation's preparedness for public health threats of all sources is a national security imperative and a top priority for this Administration.
 - HHS has had to overcome real administrative challenges and a patchwork of authorities and flexibilities while responding to the once-in-a-century COVID-19 pandemic and other recent emergencies, including the infant formula shortage and Hurricanes Ian and Fiona.
- This work is **mission-critical** for HHS, we must better respond to future outbreaks, strengthen domestic production capabilities and anticipate and prevent their worst public health and economic harms.
- We propose a suite of funding and legislative proposals to strengthen capabilities across early threat detection, supplies and medical countermeasures, workforce, recovery, and core infrastructure and capabilities.
- This includes discretionary investments and \$20 billion in mandatory funding requested across HHS public health agencies to prepare for pandemics and other biological threats. Together, these proposals will help bridge key gaps and barriers to enable a robust and timely response to future emergencies.
- I stand ready and eager to discuss the path forward with Congress.

QUESTIONS:

Q: Last Congress, we passed the PREVENT Pandemics Act, didn't that get HHS the authorities it needs to better respond to emerging public health threats?

- First, I want to thank Congress for working on bipartisan basis to support HHS work on pandemic prevention.
- PREVENTs took us one step forward, but the proposal in the FY2024 budget and Congress' work to reauthorize the Pandemic All-Hazards and Prevention Act (PAHPA) will provide enduring ability for the department to leverage the processes we know worked from COVID-19, like DOD's contracting authority for rapid research, and development and procurement of vaccines and medical countermeasures. HHS will be able to leverage to prepare and respond to future public health threats.

Q: Right now, the Centers for Disease Control and Prevention (CDC) do not have an explicit authorization. Do you think Congress should authorize the CDC and if so what should it look like?

- CDC launched Moving Forward to strengthen CDC by strategically building on lessons learned during the COVID-19 pandemic to break down silos, reduce bureaucracy, and improve accountability.
- This effort will be critical to deliver health information more clearly and quickly to policy makers and American. We're already seeing the benefits of this effort:
 - o CDC was the first in the world to produce data showing real-world effectiveness of the JYNNEOS vaccine for mpox.
 - o Two public-facing databases went live in April 2022 that provide public health practitioners and the public with critical data about non-fatal overdoses and overdose deaths to tailor interventions in their communities.
- As CDC makes the changes it can internally, we also need help from Congress through funding and new authority to fully deliver on its mission of protecting the health, safety, and security of Americans.

Q: Why is the Pandemic Preparedness Mandatory Proposal \$20 billion less? If this is mission critical why are you proposing less funding to achieve the same goals?

- The Administration remains committed to transforming the way we prepare for and respond to pandemic and other biological threats. That's why we are again asking Congress to enact bold legislation.
- The \$20 billion proposal in the FY 2024 budget is a targeted investment. While it cannot do everything, it will allow for significant progress toward meeting the Administration's preparedness goals, as outlined in the National Biodefense Strategy and Implementation Plan and American Pandemic Preparedness plan.

Q: U.S. intelligence assessments point to the possibility that SARS-CoV-2 originated from a leak at the Wuhan Institute of Virology (WIV). Did HHS/NIH fund work at WIV that resulted in the pandemic?

- NO. NIH has never approved any research that would make a coronavirus more dangerous to humans. The body of science reported—including the bat coronavirus sequences published in the scientific literature—showed that the viruses studied at WIV under the NIH grant were evolutionarily quite distant from SARS-CoV-2 and could not have been the source of SARS-CoV-2.
- The origin of SARS-CoV-2 virus has not been identified, despite intensive efforts. It took 14 years for scientists to find a single bat population that contained all the necessary genetic components of SARS-CoV, the virus that caused the 2003 SARS epidemic. We still do not know the origins of the 2014 Ebola outbreak.
- HHS strongly supports efforts to identify the SARS-CoV-2 origin.

Q: What is HHS/NIH doing to ensure biosafety and biosecurity of research involving pandemic pathogens?

- HHS/NIH is committed to ensuring the safety and security of the work we support. The U.S. has a robust biosafety and biosecurity oversight system that is predicated on identifying and assessing benefits and risks, and appropriately mitigating risks at both the Federal and institutional levels. We periodically review, and as needed, update our oversight frameworks to help ensure our biosecurity oversight frameworks keep pace with rapid advances in science.
- In February 2022, HHS tasked the National Science Advisory Board for Biosecurity (NSABB), a federal advisory committee, with reviewing the scope and effectiveness of two major U.S. biosecurity policy frameworks governing research with enhanced potential pandemic pathogens and dual use research of concern.
- The NSABB's final report was delivered in March 2023. NSABB findings and recommendations will inform ongoing USG policy deliberations.

Q: Did the NSABB consider the origins of the SARS-CoV-2 pandemic and NIH's funding of research in China?

- No, investigating the pandemic's origin was not the role of the NSABB and many other investigative bodies have been tasked with this charge.

Q: Given the potential risks, why does HHS/NIH support research involving potential pandemic pathogens?

- Research involving potential pandemic pathogens can help us understand the fundamental nature of human-pathogen interactions, assess the pandemic potential of emerging infectious agents such as viruses, and inform public health and preparedness efforts, including surveillance and the development of vaccines and medical countermeasures.

- While such research is inherently risky and requires strict oversight, the risk of not doing this type of research and not being prepared for the next pandemic is also high.

Q: Why does HHS/NIH support pathogen research in foreign countries?

- HHS/NIH supports research to better understand the characteristics of animal viruses that have the potential to spill over to humans and cause widespread disease. We must collaborate with researchers in other countries where these viruses are prevalent because once a virus spreads to humans, it is not contained by geographical boundaries. Our support ensures that the information will be shared.
- This has helped us to assess the pandemic potential of emerging infectious pathogens, including coronaviruses that have caused SARS and MERS. This is our best path to inform the development of medical countermeasures such as vaccines. It would be irresponsible for us not to do this work.
- In fact, this body of work has helped make it possible for the U.S. government to move so quickly to get a COVID-19 vaccine in an unprecedented timeframe of just 11 months. Countless lives have been saved as a result.

Program Information

The Department's approach to Pandemic All-Hazards Preparedness Act (PAHPA) is guided by three strategic objectives:

1. using data to enhance early detection and response to emerging public health threats and supply disruptions;
2. investing in domestic manufacturing capacity, research, development, and deployment of safe, effective medical countermeasures; and
3. facilitating rapid recruitment, deployment, and retention of a response-ready workforce.

These objectives also support the transformative goals for pandemic preparedness and for medical product supply chain resilience under the Administration's *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* and its *National Strategy for a Resilient Public Health Supply Chain*.

Under each of these objectives, we are requesting specific new or expanded authorities that will improve our odds of success.

Enhancing early detection and response

- During the pandemic, we experienced repeated and protracted difficulties obtaining accurate, real-time data about disease hotspots and emerging product shortages. For example, during COVID-19, it took 6 months to sign 61 Data Use Agreements, and during the mpox response, it took over 6 weeks to sign the same number of Data Use Agreements before the federal government could get critical data from the states.
 - o In some cases, negotiating an individual agreement with a state or local IIS has taken FDA 18 months to two years; the Agency has not been able to negotiate individual agreements with many of the IIS entities, meaning that we do not have complete data for some jurisdictions.
- Additionally, when FDA requests records from IIS or Electronic Health Records Systems to verify adverse events detected by the Biologics Effectiveness and Safety (BEST) Initiative databases it has taken FDA around 8-12 weeks in some cases to receive voluntary access to these records.
- To ensure a nimble response to future threats, we need the authority for HHS agencies to effectively collect and coordinate public health and human services data.
 - o This includes for CDC, FDA, and CMS to collect data from laboratories, providers, data partners, and state and local health departments, in a standard way, and to share that data with other federal response agencies.
 - o And, for FDA to require drug and medical device manufacturers to report basic information like shifts in drug demand and the locations of their suppliers, to improve end-to-end supply chain visibility and enhance our ability to predict and mitigate critical medical product shortages.

Investing in domestic manufacturing capacity

- To stay competitive with China and to advance the National Biodefense Strategy and the National Strategy for a Resilient Public Health Supply Chain, it's also imperative that we gain new authorities to expand domestic manufacturing capacity and continue to fund long-term innovation in the development of medical countermeasures.
- This also means gaining new authorities to procure innovative commercial and experimental products and to execute competitive purchases of vaccines, diagnostics, PPE, and other medical supplies for which we have been previously reliant on the Department of Defense.
- It also means additional oversight tools to help ensure the safety and accountability of manufactured products.

Strengthening workforce capacity

- Finally – the last few years showed us the tremendous capabilities and dedication of the Department's public health workforce, but they also exposed several structural impediments to our ability to attract, retain, engage, and train the skilled workforce we need to prepare for and respond to public health emergencies.
- We need additional tools that would enable us to rapidly surge our workforce capacity following events like natural disasters and disease outbreaks. We need direct hiring authority for HHS and the flexibility to expedite and streamline the process for hiring scientists, clinicians, and other public health experts at a salary competitive with the broader market. Absent updated authority, HHS will need to continue to rely on lengthy approval and renewal processes which slow down the agency's efforts to move quickly. For example, during the COVID response, CDC was required to submit an extension for direct hires that took approximately six months to approve while CDC was in dire need of staff.
- We also need authorities similar to other response operations—like FEMA, which benefits from additional pay and hiring authorities. Consistency will enhance retention and recruitment as well as ensure the Department has equitable hiring capacity and capability.

NIH Background

- HHS works closely with our federal and nonfederal partners to strengthen U.S. pandemic preparedness. This includes ongoing activities associated with:
 - the National Biodefense Strategy and Implementation Plan for Countering Biological Threats,
 - Enhancing Pandemic Preparedness, and Achieving Global Health Security, American Pandemic Preparedness: Transforming Our Capabilities, and
 - the U.S. Global Health Security Strategy.
- Building on vaccine research and development successes during the COVID-19 pandemic, NIH investments in pandemic preparedness will accelerate early-stage

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discovery, design, and development of vaccines, vaccine platforms, and therapeutics for pathogens of concern.

- To develop the next generation of protective countermeasures, NIH will establish, expand, and/or improve large and rapidly scalable clinical trials networks and infrastructure to generate real-world evidence on the performance of vaccines, therapeutics, and diagnostics.

Public Health Emergency - Uninsured Program

TALKING POINTS:

- The Biden-Harris Administration is committed to ensuring continued access to COVID-19 vaccines and treatments for all Americans.
- Congress established funding for the Uninsured Program to provide claims reimbursement to health care providers for during the COVID-19 pandemic testing, treatment and vaccinations administration for uninsured individuals.
- As of March 1, 2023, HHS has made **\$24.5 billion in claims reimbursement payments** to providers for testing, treatment, and vaccination of uninsured individuals. Including:
 - Over 11.3 billion claims for testing;
 - 5.8 billion claims for treatment; and
 - 1.6 billion claims for vaccine administration.
- HHS has processed and paid nearly all eligible claims submitted to the program by the deadlines. There are a small number of claims remaining requiring technical, administrative adjustments or program integrity review.
- Due to a lack of sufficient funding, in March 2022, HHS announced that the COVID-19 Uninsured Program would have to stop accepting claims. To date, no additional funding has been appropriated for the Uninsured Program.

QUESTIONS:

Q: How much has been spent on the Uninsured Program?

- As of March 1, 2023, HHS has made \$24.5 billion in claims reimbursement payments to providers for testing, treatment, and vaccination of uninsured individuals.

Q: How much is money is left in the Uninsured Program?

- On March 15, 2022, the White House announced that the COVID-19 Uninsured Program would have to stop accepting claims for testing and treatment on March 22, 2022, and stop accepting claims for vaccination administration on April 5, 2022, due to a lack of sufficient funding.
- To date, no additional funding has been appropriated for the Uninsured Program, and claims are no longer being accepted.

Q: Is HHS still processing claims in the Uninsured Program?

- HHS has processed and paid nearly all eligible claims submitted to the program by the deadlines. There are a small number of claims remaining requiring technical, administrative adjustments or program integrity review.

Q: How did HHS prevent fraud or abuse in the Uninsured Program?

- HHS implemented numerous program integrity and fraud prevention measures as part of the Uninsured Program. To participate in the Uninsured Program, providers were required to undergo multiple verification steps, including submitting their *National Provider Identifier* (NPI) and their Tax Identification Number for validation. Providers also were checked against several provider compliance and exclusion lists to assess whether they are in good standing.
- Specifically, HHS excludes providers who:
 - o Were excluded from participation in Medicare, Medicaid, or other Federal health care programs;
 - o Were on the List of Excluded Individuals/Entities from HHS's Office of the Inspector General; or
 - o Were terminated from participation in Medicare or precluded from receiving payment through Medicare Advantage or Medicare Part D; or
 - o Had their Medicare billing privileges revoked.
- Providers who are suspected to be or found to be out of compliance with the terms and conditions of the Uninsured Program can be subject to holds on reimbursements, post-payment reviews, termination from the program, recovery of funds, and referral to law enforcement as appropriate.

Program Information

BACKGROUND:

- To implement the Families First Coronavirus Response Act, in April 2020, HHS launched the Uninsured Program, providing claims reimbursement to cover testing costs and related items and services, as defined in the statute, for uninsured individuals. Funds from the Paycheck Protection Program and Health Care Enhancement Act (PPPHCEA) and American Rescue Plan Act have also covered testing costs and related items and services for this program.
- Further, in 2020, the Trump Administration allocated Provider Relief Fund resources to expand the Uninsured Program to include coverage of COVID-19 treatment and later vaccine administration for individuals who are uninsured.
- With additional funding appropriated through the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the PPPHCEA, the Uninsured Program has continued to support COVID-19 testing, testing-related items and services, COVID-19 treatment services, vaccine administration fees, and, more recently, oral antiviral dispensing fees for the uninsured. Additional funding from the American Rescue Plan also supported testing claims reimbursement.
- On March 15, 2022, the White House announced that the COVID-19 Uninsured Program would have to stop accepting claims for testing and treatment on March 22, 2022, and stop accepting claims for vaccination administration on April 5, 2022, due to a lack of sufficient funding.
- To date, no additional funding has been appropriated for the Uninsured Program, and claims are no longer being accepted. HHS has now processed and paid nearly all eligible claims submitted to the COVID-19 Uninsured Program by the program deadlines. There are a small number of claims remaining requiring technical, administrative adjustments or program integrity review.

Public Health Emergency and Telehealth (not controlled substances)

TALKING POINTS:

- **PHE END BUDGET:**

- **Medicaid**

- In FY 2024, the federal government will spend an estimated \$556.2 billion on the Medicaid program, a decrease of \$51.5 billion below 2023. This decrease in spending is due to the end of the continuous enrollment condition in Medicaid on March 31, 2023.
 - CMS continues to work with states on their Medicaid and CHIP renewal plans and system readiness as the continuous enrollment condition comes to an end on March 1, 2023. CMS also focuses on continuity of coverage and streamlining transition to alternate forms of coverage for beneficiaries by launching two outreach and information campaigns targeted towards beneficiaries, and announcing a marketplace special enrollment period for individuals who lose Medicaid coverage during the unwinding period.

- **Private Insurance**

- The FY 2024 budget includes \$281 million for Marketplace consumer information and outreach and \$141 million for Navigators. This includes paid media and direct consumer enrollment assistance, which will support the transition of eligible Medicaid recipients to Marketplace coverage.

- **Discretionary**

- Digital Healthcare Research: +\$2 million above FY 2023 enacted, for a total of \$18 million for AHRQ's Digital Healthcare Research Program. Increases will be used to establish Centers of Excellence in Telehealth Implementation that will generate essential new evidence to understand telehealth's effect on access, equity, and quality and inform key policy decisions to maximize telehealth's impact.

- **TELEHEALTH:**

- **Medicare**

- Most of the current Medicare telehealth flexibilities that Medicare beneficiaries have relied on over the past two years will remain in place through December 2024 due to the Consolidated Appropriations Act, 2023 passed by Congress in December 2022, such as:
 - Access to telehealth services in any geographic area in the United States, rather than only those in rural areas.
 - Receive in-home telehealth visits that Medicare pays for rather than traveling to a health care facility.
 - Cover certain telehealth visits delivered audio-only (such as a telephone) if someone is unable to use both audio and video, such as a smartphone or computer.
 - Medicare Advantage plans may offer additional telehealth benefits.

- Additionally, after December 31, 2024 when these flexibilities expire, some Accountable Care Organizations may offer telehealth services that allow primary care doctors to care for patients without an in-person visit, no matter where they live.
- **Medicaid**
 - States have significant flexibility with respect to covering and paying for Medicaid services delivered via telehealth. State requirements for approved state plan amendments vary as outlined in CMS' Medicaid & CHIP Telehealth Toolkit. This flexibility was available prior to the COVID-19 PHE and will continue to be available after the PHE ends. Like Medicare, these telehealth flexibilities provide a vital lifeline to many individuals receiving Medicaid, particularly for persons in rural areas and those with limited mobility.
- **Private Insurance**
 - During the PHE, high deductible health plans were granted a temporary safe harbor to cover telehealth and remote care services on a first dollar basis without jeopardizing Health Savings Account contributions. This safe harbor has been extended through December 31, 2024 due to the Consolidated Appropriations Act, 2023.

QUESTIONS:

Q: How will the transition from the public health emergency affect Medicaid Telehealth budget?

A: Under Medicaid statute, telehealth is a mode of delivery, not a separate services. States have flexibility to continue pandemic changes they may have made under current law.

Q: Why does the HHS budget not permanently extend telehealth flexibilities in Medicare?

A: HHS is committed to supporting a temporary extension of some broader telehealth coverage flexibilities under Medicare beyond the COVID-19 Public Health Emergency. However, we also support Congressional mandates to study whether Medicare's telehealth flexibilities promote proper use and access to care. Additionally, HHS continues to work closely with Congress to provide technical assistance on several introduced telehealth bills and others that are in development. We urge Congress to extend permanently several high priority Medicare telehealth provisions:

- (1) Coverage of services with the patient's home as an originating site;
- (2) Federally Qualified Health Centers and Rural Health Clinics provisions allowing both to serve as distant sites;
- (3) Payment parity for behavioral telehealth services, based on strong evidence that telehealth is as effective as standard in-person treatment in this area; and
- (4) Audio-only access for patients whose circumstances necessitate that as the preferred mode of care delivery (whether due to broadband limitations, lack of video-enabled devices, data limitations, and/or beneficiary preference).

Q: What telehealth flexibilities remain in Medicaid after the PHE ends?

A: States generally have broad flexibility to cover and pay for services provided via telehealth in their Medicaid program. States may apply to CMS for waivers or state plan amendments to continue telehealth flexibilities that expire as a result of the end of the PHE.

Q: What telehealth flexibilities remain in Marketplace plans after the PHE ends?

A: As is currently the case during the PHE, coverage for telehealth and other remote care services will vary by private insurance plan after the end of the PHE. When covered, private insurance may impose cost-sharing, prior authorization, or other forms of medical management on telehealth and other remote care services.

Program Information

- **The Budget invests in telehealth, policy-relevant health services research, and the expansion of access to quality care** by investing +\$10 million for a total of \$45 million in HRSA Office for the Advancement of Telehealth.
 - HRSA will support the continuation of 38 existing grantees, and 27 new competitive grants to strengthen the networks and the technical assistance providers that support effective implementation of telehealth services.
 - The request will also fund a contract for the Telehealth Data Collection Infrastructure, which is critical in allowing HRSA to track funding, projects, and data for telehealth services within HRSA.
- AHRQ's legislatively authorized role is to fund research on whether and how digital healthcare innovations improve healthcare quality. The budget proposes \$18 million, an increase of \$2 million, to allow AHRQ to establish Centers of Excellence in Telehealthcare Implementation dedicated to advancing a telehealth research agenda to evaluate the impact of various telehealthcare models and approaches that will improve care equity, access to care, care quality, patient-clinician communication, and health outcomes with a focus on primary care services

BACKGROUND:

HHS took a range of administrative steps to expedite the adoption and awareness of telehealth during the COVID-19 pandemic. Some of these Medicare and Medicaid telehealth flexibilities have been made permanent while others are temporary. The Department has recently released a [COVID-19 PHE Transition Roadmap Fact Sheet](#) as well as continues to update the public-facing website, [Telehealth.HHS.gov](https://telehealth.hhs.gov), which includes a comprehensive summary of the telehealth flexibilities and policies after the COVID-19 Public Health Emergency (PHE), including the following categories:

- [Permanent Medicare changes](#)
- [Temporary Medicare changes through December 31, 2024](#)
- [Temporary changes through the end of the COVID-19 public health emergency](#)

Public Health Emergency - Unwinding

TALKING POINTS:

- While COVID is not over, because of the Biden Administration's whole of government response since day 1, we distributed over **965 million vaccines**, and now we are in a position where we can effectively lift the Public Health Emergency (PHE) and the National Emergency.
- The Administration will now execute the process of a smooth **operational wind down** of those emergency policies enabled by the COVID-19 emergency declarations, including waivers that give healthcare providers and systems the flexibilities needed for operations and staffing to provide expanded and continued access to high quality of care.
- We will continue to communicate to States, health care providers, and the public in the coming days and months, what that process means and working with states and jurisdictions to ensure an orderly transition.

QUESTIONS:

Q: How will this impact the uninsured?

- This decision to unwind the PHE and lift the National Emergency is distinct from our longer-term planning on the transition of vaccines and additional therapeutics to the commercial market.
- Right now, COVID-19 vaccines and certain therapeutics remain free and widely available. We will be transitioning to commercial markets later this year, but making sure that the uninsured have continued access to vaccines and treatments is one of the Administration's highest priorities.

Q: What about 1135 waivers? What about telehealth?

- CMS has been working with stakeholders over the last few months to understand the flexibilities enabled by these 1135 waivers and other mechanisms and plan for their eventual end.
- Last August, CMS developed a roadmap for the eventual end of the waivers and flexibilities, and shared information on what health care facilities and providers can do to prepare for future events.
- Similar to the guidance CMS has made available to states, CMS released fact sheets that will help the health care sector transition to standard operations once the PHE ends.
- Regarding telehealth, certain major flexibilities in Medicare coverage for certain telehealth services will remain in effect through at least December 31, 2024.
- However, ending the PHE would terminate flexibilities in the prescribing of certain controlled substances via telehealth. The Drug Enforcement Administration has proposed rulemaking in this area, and we look forward to working with our DOJ colleagues and stakeholders on a final rule.

Q: What data powers does this relinquish?

- The PHE has facilitated our monitoring of variants by allowing the Centers for Disease Control and Prevention (CDC) to impose requirements for data reporting.
- CDC has been working with jurisdictions to continue to voluntarily provide data; the wind down will give CDC the time that it needs to continue to negotiate agreements with all jurisdictions.

Q: What is the timeline for commercialization of the COVID-19 vaccines and treatments?

- While there are many considerations and timelines may shift based on the trajectory of the virus, we anticipate that the transition of vaccines to more traditional pathways for procurement, distribution, and payment will occur in early fall.
- Some of those considerations include what will be authorized and recommended by FDA and CDC, and what will align with a strain change for potential variants.
- Provided that one is authorized and recommended by FDA and CDC, we expect this transition will align with a possible strain change that accounts for any potential variants.
- The treatments transition to commercial markets will vary by product and will likely occur for at least one product before the end of the year.
- The USG is working on determining the exact dates for COVID-19 vaccines and therapeutics. We will share more information about timelines when we are able.

Q: What is the impact of the end of the COVID-19 Public Health Emergency (PHE) on May 11 on access and costs to COVID-19 vaccines and treatments?

- The PHE does not affect the transition of vaccines and treatments to commercial markets.
- In February 2023, HHS Secretary Becerra renewed the PHE for one last 90-day period planned to end at the end of the day on May 11, 2023. This action is based on the most recent COVID-19 trends and is consistent with the Administration statement on January 30, 2023, that the PHE is planned to end at the end of the day on May 11.
- In the past, HHS has committed to providing 60 days-notice in advance of ending the PHE. To foster a smooth transition, HHS has given 90 days-notice instead.
- Even with the planned end of the PHE at the end of the day on May 11, on May 12, all vaccines and treatments purchased by the U.S. government will continue to be distributed and available for free to U.S. residents. The PHE itself does not affect the supply or distribution of our vaccines or treatments. It also does not affect FDA's ability to authorize various products, including tests, treatments, or vaccines for emergency use.

Q: How will commercialization change the accessibility of COVID-19 vaccines and treatments?

- COVID-19 remains a significant public health priority for the Administration and for HHS. We know so many are still affected by COVID-19, particularly seniors and people

with disabilities. We remain committed to maximizing availability of COVID-19 vaccines and treatments.

- Our intention is that vaccines and treatments will remain available from all of the places U.S. residents currently receive them, whether it's at their pharmacy or their health care provider.
- Vaccines will remain free for most U.S. residents through the Vaccines for Children Program, Children's Health Insurance Program, most commercial insurance, Medicare, and Medicaid programs.
- Those with Medicare, Medicaid, and most private insurance will be able to access covered treatments, potentially with cost-sharing.

Q. How will Vaccines be available for the un- and under-insured?

- CDC's Vaccines for Children Program will provide coverage for uninsured children as it does for other routine vaccinations.
- HHS is actively working with vaccine and treatment manufacturers to ensure that Patient Assistance Programs that provide free access to these products are easy to use and broadly accessible.
- HHS continues to invest in health systems and programs that support vaccine access and outreach in underserved communities – such as Federally Qualified Health Centers, Rural Health Clinics, and state and local health departments. These networks can be leveraged for access to COVID-19 vaccines and therapeutics as well as other needed medicines.

Physician Payments

TALKING POINTS:

- HHS values the critical role that physicians and other health care professionals play in health care delivery.
- Ensuring adequate Medicare payments for providers is essential to maintain beneficiary access to high-quality and affordable health care.
- I appreciate Congress' leadership in the Consolidated Appropriations Act, 2023 to (1) provide temporary, one-year increases payment amounts for all services under the physician fee schedule by 2.5 percent in 2023 and 1.25 percent in 2024 and (2) extend incentive payments for clinicians who are qualifying participants in advanced alternative payment models for one year through 2025, though at a lower rate (3.5 percent rather than 5 percent).

QUESTIONS:

Q: Medicare cuts in physician payments are driving health system consolidation, exacerbating provider shortages and access issues, and hurting our health system's responsiveness and capabilities for future pandemics. Why did CMS cut physician payments again for 2023?

- The Biden-Harris Administration is committed to protecting and strengthening Medicare so that Americans of every generation can count on it and ensuring that providers receive appropriate payments is a critical part of our efforts.
- HHS is required to base payments for services under the physician fee schedule on the relative resource costs involved in furnishing a service, and the fee schedule is subject to statutory budget-neutrality requirements.
- HHS does not have the legal authority to implement increases in payment outside of budget neutrality without additional action taken by Congress.

Program Information

Physician Fee Schedule

- Every year, CMS issues a rule that includes updates and policy changes for Medicare payments under the Physician Fee Schedule, and other Medicare Part B issues, effective on or after January 1 the following year.
- The Physician Fee Schedule pays for services that are furnished in various settings, including most outpatient settings, and for several types of suppliers for technical services, most often in settings for which no institutional payment is made.
- For most services furnished in a physician's office, Medicare makes payment to physicians and other professionals at a single rate based on the full range of resources involved in furnishing the service, including administrative activities. In contrast, PFS rates paid to physicians and other billing practitioners in facility settings, such as a hospital outpatient department or an ambulatory surgical center, reflect only the portion of the resources typically incurred by the practitioner in the course of furnishing the service.
- Payments are based on the relative resources typically used to furnish the service. Geographic adjusters are also applied to account for variation in practice costs by geographic area. Payment rates are calculated to include an overall payment update, including budget neutrality adjustments, specified by statute.

Consolidated Appropriations Act, 2023

SEC. 4111. EXTENDING INCENTIVE PAYMENTS FOR PARTICIPATION IN ELIGIBLE ALTERNATIVE PAYMENT MODELS.

Current Law: Beginning with calendar year 2019 and ending with 2024, qualifying alternative payment model (APM) participants are eligible to receive an incentive payment of 5 percent of payments for covered professional services for the preceding year.

With respect to a year, qualifying APM participants are those for whom a specified percentage of Medicare payments or patients (or, from 2021 onward, payments made by both Medicare and other payers) in a performance year for covered professional services are attributable to an Advanced APM. Payment years are two years after performance years, e.g., qualifying APM participants with respect to 2019 qualify based on 2017 performance.

Provision: For calendar year 2025, allows qualifying APM participants to receive an incentive payment of 3.5 percent. Maintains the same threshold level (specified percentage of payments or patients) that applies for 2024 in order to be a qualified APM participant for 2025.

SEC. 4112. EXTENSION OF SUPPORT FOR PHYSICIANS AND OTHER PROFESSIONALS IN ADJUSTING TO MEDICARE PAYMENT CHANGES.

Current Law: For calendar year 2021 and 2022, Congress enacted legislation providing for temporary, one-year increases of 3.75 and 3 percent, respectively, for all services under the Medicare physician fee schedule (PFS). These increases are not built into the baseline for determining future fee schedules.

Provision: Increases fee schedules across-the-board for all services under the PFS in calendar years 2023 and 2024 by 2.5 percent and 1.25 percent, respectively. The increases in fee schedules are exempt from budget neutrality requirements and would not factor into any determinations of fee schedule amounts in future years.

Effective Date: Effective January 1, 2023

PrEP Delivery Program to end HIV Epidemic

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
PrEP Delivery Program Cost	-	237	+237
Total Program Level	-	237	+237

Note: The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year.

TALKING POINTS:

- The budget includes a mandatory proposal to invest \$9.8 billion over 10 years to create a national financing and delivery program so anyone who needs Pre-exposure Prophylaxis (PrEP) has access via community providers.
- Fewer than 1 in 4 people who could benefit from PrEP are receiving the medication. Preliminary CDC data show that only 9 percent of the nearly 469,000 Black individuals who could benefit from PrEP received a prescription in 2020 and only 16 percent of the nearly 313,000 Hispanic and Latino individuals who could benefit from PrEP received a prescription.

QUESTIONS:

Q: The Budget includes a new PrEP for All proposal. What will happen to the current PrEP donation program?

A: The PrEP for All proposal builds on the current donation program to expand its benefits and purposes to meet anyone in need of care.

Q: What is the future cost of this program?

A: The program invests \$9.8 billion over the next ten years to expand access to PrEP for individuals at high risk of HIV infections across the United States.

Q: Will this program end the HIV/AIDS epidemic?

A: The program aims to end the HIV/AIDS epidemic by 2030, with a commitment to 75% infection reduction by 2025.

Program Information

The Budget increase invests \$237 million to end HIV/AIDS epidemic in the United States by 2030.

- Funding for the delivery program increases in subsequent years, resulting in a ten-year program cost of \$9.835 billion in budget authority over ten years.
- The Budget also removes barriers to accessing PrEP under Medicaid, resulting in \$10.2 billion in savings.
 - Net of the PrEP Delivery Program and removing barriers to PrEP under Medicaid saves \$577 million over 10 years while vastly expanding prevention, saving health care costs, and saving lives.

Program Integrity

(Dollars in Millions)

Activity	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Discretionary HCFAC			
CMS	666	667	+1
ACL ¹	0	35	+35
OIG	105	112	+7
DOJ	122	122	+0
Subtotal, Discretionary HCFAC	893	937	+44
Mandatory HCFAC	1,523	1,812	+289
Total, HCFAC Program Level	2,416	2,749	+333
Medicaid Integrity Program	95	100	+5

¹ACL's FY 2023 Enacted amount (\$35 million) for the Senior Medicare Patrol program is included in CMS's FY 2023 Enacted amount.

TOPLINE MESSAGES:

- The budget includes \$5.2 billion⁴ in new investment over ten years in combined mandatory and discretionary Health Care Fraud and Abuse Control (HCFAC) spending.
- This robust investment in fraud prevention and enforcement will yield a return-on-investment of \$19.7 billion over ten years.
- Increased investment is needed to keep pace with the size, scope and complexity of healthcare fraud.
- Without additional resources, CMS, the HHS Office of Inspector General, and DOJ may have to forgo investigating serious instances of fraud, waste, and abuse.

QUESTIONS:

Q: Why are you seeking such a large increase in HCFAC funding? Is this an indication that the Administration has allowed healthcare fraud to run rampant?

- No. The increase in HCFAC funding reflects the Administration's commitment to fighting fraud and the belief that this investment will pay off in significant returns to Medicare Trust Funds and the Treasury.
- Growth in Medicare and Medicaid benefit spending has been more than double growth in HCFAC oversight spending in the last four years alone.

⁴ The printed draft of the Budget in Brief has an error showing this number as \$5.5 billion rather than the correct figure of \$5.2 billion; the on-line version of the BIB will correct that error.

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- Additionally, this funding is necessary to keep pace with the growing scope and complexity of fraud schemes.
- This investment will more than pay for itself. Medicare program integrity activities currently yield an \$8 to \$1 return-on-investment. Law enforcement program integrity activities currently generate a \$4 to \$1 return-on-investment.
- Our budget makes the biggest investment in health care fraud and abuse prevention and enforcement since the Affordable Care Act. We increase spending to combat health care fraud and abuse by 20 percent over ten years, compared to the 5 percent increase Congress provided for this activity in 2010. That is a four-fold difference. About two-thirds of the funding increase goes toward prevention, one-third toward enforcement.

Program Information

Mandatory HCFAC

- **The budget invests \$3.8 billion in mandatory HCFAC funding over the next ten years** to help CMS, the Inspector General, and DOJ more effectively combat fraud, waste, and abuse.
- This would be the first major investment in mandatory HCFAC since 2010.
- This new investment will yield a \$5.4 billion return-on-investment over ten years.
- Fraud and abuse oversight is lagging Medicare and Medicaid spending growth, limiting our ability to effectively combat health care fraud, waste, and abuse:
 - Only 1 out of every 2,000 fee-for-service Medicare claims undergo medical review by CMS despite a \$3 to \$1 return-on-investment.
 - In 2022, OIG did not have resources to act on 400 civil and criminal cases, 648 CMS referrals, and nearly 3,500 hotline complaints.
 - The DOJ workforce lags behind potential enforcement caseloads and FBI special agent staffing has been static since 2015.
- The budget grows all but one mandatory HCFAC funding stream by 20 percent over current law baseline levels; the HHS Wedge stream would grow by 10 percent.
- Additional mandatory HCFAC investment will support top priorities such as:
 - Increased Medicare fee-for-service medical review to identify improper payments;
 - Oversight of care provided in nursing home or home-based settings;
 - Law enforcement and prosecution activities to combat existing and emerging fraud schemes;
 - Investigations and forensic audits to identify fraud and abuse;
 - Increased specialized staffing for enforcement and oversight; and,
 - Cutting-edge data analytics to detect trends and outliers.
- The mandatory HCFAC proposal also makes modifications to HCFAC statutory purposes, definitions, and reporting requirements that have not been changed since 1996, including:
 - Expanding the HHS Office of Inspector General investigations of CMS programs to include Marketplaces and related activities, such as premium tax credits, as their current authority is limited to Medicare and Medicaid activities;
 - Clarifying that HCFAC allowable purposes apply to both public and private plans given there is some confusion among healthcare prosecutors that these authorities only apply to Medicare and Medicaid; and
 - Including the Children's Health Insurance Program in the Medi-Medi data match program so that CMS can audit and investigate the \$20 billion that providers bill to this program.

Discretionary HCFAC

- **The budget increases investments in discretionary HCFAC funding by \$1.4 billion over the next ten years.**
- In FY 2024, the budget increases spending across HCFAC partners by +\$44 million compared to the FY 2023 Enacted level, including:

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- CMS: +\$1 million above FY 2023 Enacted, for a total of \$667 million primarily for additional Medicare fee-for-service medical review.
- ACL: +\$35 million above FY 2023 Enacted, for a total of \$35 million for the Senior Medicare Patrol program to combat health care fraud and abuse. The budget assumes discrete funding for ACL's Senior Medicare patrol.
- OIG: +\$7 million above FY 2023 Enacted, for a total of \$112 million to support OIG investigative efforts.
- DOJ: flat with FY 2023 Enacted, for a total of \$122 million for fraud and abuse law enforcement and prosecution activities.
- The budget assumes the \$937 million discretionary HCFAC funding base in FY 2024 will grow with inflation over the next decade, as part of a federal-wide policy across several program integrity programs. The actuaries have conservatively assumed that ongoing increased investment in program integrity activities will yield a positive rate of return. The budget assumes net Medicare and Medicaid savings of \$14.3 billion from the long-term growth in this investment.

Medicaid Integrity Program

- The budget provides a total of \$100 million in mandatory funding in FY 2024 for the Medicaid Integrity Program. Funded activities include reviews, audits, education activities, and technical support to states. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded by the HCFAC Program.

Marketplace Program Integrity

- The FY 2024 budget includes \$44 million for CMS Marketplace program integrity efforts, +\$4 million above the FY 2023 Enacted level. The Marketplaces are important avenues for consumers to obtain health insurance coverage and get financial assistance, in the form of advance premium tax credits, to help pay for insurance premiums. CMS investigates complaints and leads from health insurance issuers and other partners to protect consumers. Using data analytics, CMS supports and prioritizes investigations that aim to safeguard the integrity of the Marketplace and expenditures of federal dollars. CMS also supports the measurement and reporting of estimated improper payments in the Advance Premium Tax Credit program.

HHS Office of Inspector General (OIG)

- The budget requests \$112 million for OIG to continue using risk-assessment to focus enforcement and oversight on protecting the Medicare and Medicaid programs and beneficiaries and patients from fraud and abuse. This funding will also ensure sound program management, payment accuracy, patient safety, and quality of care. Areas of focus will continue to include nursing homes, home and community-based services, managed care, telehealth, health equity, and affordability of prescription drugs.

Other Budget Program Integrity Proposals

- The budget includes five additional program integrity legislative proposals that aim to restructure the mandatory HCFAC program, expand nursing home oversight, and promote good governance by the following:
 - Require additional disclosures from private equity or real estate investment trust ownership to improve quality of care in skilled nursing facilities;
 - Implement targeted risk-adjustment pre-payment review in Medicare Advantage;
 - Expand tools to identify and investigate fraud in the Medicare Advantage program;
 - Ensure providers that violate Medicare safety requirements and have harmed patients cannot quickly reenter the program; and
 - Prohibit unsolicited Medicare beneficiary contacts to address general emerging fraud threats.

Provider Relief Fund

TALKING POINTS:

- The Provider Relief Fund (PRF) was developed and launched mere weeks after the CARES Act passed, at the height of the initial challenges related to the pandemic and at a time of great uncertainty surrounding the impact that COVID-19 would have on the health care system.
- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding. This includes:
 - \$15.4 billion to over 90,000 providers in Phase 4
 - \$8.3 billion in ARP Rural payments to 47,000 providers with patients who live in rural areas
 - Nearly \$20 billion to about 65,500 providers through Phase 3
 - About \$13 billion to safety net hospitals
 - Almost \$21 billion to providers in “COVID-19 Hotspots” at different times during the pandemic
 - Nearly \$5 billion to skilled nursing facilities
- The Biden-Harris Administration implemented Phase 4 of the PRF allocations after the prior Administration had allocated most of the funds. In this Administration, we have focused on distributing PRF payments in a way that recognizes providers’ public payor mix and as efficiently as possible while ensuring transparency and program integrity to safeguard taxpayer dollars.
- To date, of the 106,000 applications received, HHS has **processed more than 99% of Phase 4 applications** and **100% of applications for rural** providers in the American Rescue Plan funding.

QUESTIONS:

Q: How much money is left in the Provider Relief Fund?

- All funding is fully allocated. Balances are supporting ongoing activities.
- HHS has allocated resources to reimburse health care providers for the cost of COVID-related health care through the Provider Relief Fund program. HRSA conducts a thorough, multi-step process to evaluate and verify provider claims and requests for reconsiderations. While most funds have been obligated, in some instances, HRSA’s process is not yet complete. Congress made these funds available until expended. HRSA obligates funds as payments are made.

Q: Why did HHS use PRF funds to promote vaccine confidence and vaccine outreach campaigns in December 2022?

- The campaigns launched in December 2022 supported the uninsured and most vulnerable population in accessing COVID vaccines. HHS utilized available funds to support access to critical COVID services during the winter months.

Q: Why is HHS sending debt collection letters to providers for Provider Relief Fund payments?

- PRF recipients are required to comply with reporting requirements established under the CARES Act.
- Providers who do not meet their reporting requirements or who are otherwise found out of compliance with the Terms and Conditions are subject to repayment of the funds.
- HHS has begun issuing Final Repayment Notices to providers who are non-compliant with the PRF Terms and Conditions.
- Providers who disagree with the repayment request have an opportunity to request a Decision Review of HHS's decision to seek recovery of PRF funds. Information on how providers may request a Decision Review will be included in the Final Repayment Notice.

Q: Why did PRF payments appear to benefit providers that were in stronger financial positions at the start of the pandemic?

- Due to the unprecedented nature and uncertainty at the beginning of the pandemic, Congress directed that HHS distribute PRF funds using “the most efficient payment systems practicable to provide emergency payment.”
- As a result, HHS used provider data that was readily available, including data already used by HHS agencies, or could be quickly and consistently collected to ensure that payments would be issued swiftly so the health care system could be kept afloat at a time when many health care providers were experiencing an unprecedented and abrupt loss in revenue.
- Ensuring equity and transparency in PRF payments has been a top priority for me.
- Under my leadership, we developed and implemented Phase 4 of the Provider Relief Fund. Phase 4 prioritized equity for providers serving high need communities, including by incorporating bonus payments based on the number of services provided to patients with Medicaid, Children's Health Insurance Program (CHIP), or Medicare coverage, who tend to have greater and more complex medical needs or have lower incomes.

BACKGROUND:

- Congress provided a total of \$178 billion for lost revenues and health care-related expenses attributable to coronavirus and COVID-19. Congress also provided \$8.5 billion in the American Rescue Plan for providers who serve rural patients.
- As of March 1, 2023, HHS has obligated approximately \$171.8 billion in PRF funding – most of the funding was distributed during the prior administration.
- All other funding is allocated for ongoing activities and emerging needs.
- The Biden-Harris Administration developed and implemented Phase 4 of the Provider Relief Fund and American Rescue Plan payments for rural providers.
 - o Under these phases of the program, HHS has prioritized equity for providers serving high need communities, including by incorporating bonus payments based on the amount of services provided to patients with Medicaid, Children’s Health Insurance Program (CHIP), or Medicare coverage, who tend to have greater and more complex medical needs or have lower incomes.
 - o To date, HHS has processed more than 99% of Phase 4 applications and 100% of applications for American Rescue Plan funding for rural providers.

Quality Adjusted Life Years (QALYs)

TALKING POINTS:

- Across HHS, we are working every day to address the health disparities of disabled people and ensure equal access to health care for everyone.
- There is already a prohibition on the use of quality adjusted life years in Medicare, and HHS is in full compliance.
- We are happy to work with Congress and provide technical assistance on legislation related to the use of quality adjusted life years.

If pressed on drug price negotiation

- The Inflation Reduction Act prohibits the Secretary from using quality adjusted life years for drug price negotiation.
- We will follow the statute.

Refugees and Unaccompanied Children – Budget Overview

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Transitional and Medical Services	564	1,000	+436
Refugee Support Services	307	686	+379
Unaccompanied Children	5,506	5,506	--
FY 23 Supplemental Funds	2,400	--	-2,400
FY 23 CR Anomaly Funds	1,775	--	-1,755
Contingency Funds ¹	<u>326</u>	<u>2,776</u>	<u>+2,450</u>
Subtotal, UC & Refugees	10,878	9,969	-910
Trafficking Victims and Torture Survivors	50	66	+17
Total Program Level²	10,928	10,035	-893

¹ Funding amounts are based on probabilistic scores

² FY 2023 includes \$2.4 billion in Division M (Ukrainian Supplemental) funds which are not included in budget authority.

TALKING POINTS:

- The budget provides \$10.0 billion for new arrivals and unaccompanied children. An expanded contingency fund would provide additional resources if needed for either population.
- Refugees: Continues to **rebuild the nation's resettlement capacity** by requesting an increase of +\$815 million to support 241,000 eligible new arrivals in FY 2024, including 125,000 refugees.
 - Including the contingency fund, the Budget would support 426,000 new arrivals.
- Unaccompanied Children: **Protects** unaccompanied children, moving them from the DHS border facilities to child center care settings, keeping them safe from COVID, and uniting them safely and quickly with vetted relatives or other sponsors.

QUESTIONS:

Q: Does your budget include sufficient funds to shelter all new arrivals and unaccompanied migrant children?

A: Budgeting for this program is challenging because we do not know how many people will need services in FY 2024. Because these estimates may change, it also includes a contingency fund to ensure we can respond to the unpredictable and sometimes rapidly changing nature of these populations.

- Protecting unaccompanied migrant children can be costly given their complex needs and various legal and ethical requirements. We are focused on being good stewards of tax dollars without cutting corners when it comes to the well-being of children in our care. We also owe new refugees, asylees, and other arrivals a chance to become self-supporting in their new home country.
- The budget includes sufficient discretionary funds to provide initial support for 241,000 new refugee, asylee, and other arrivals and for 16,000 standard shelter beds.
- If additional resources are needed for either population, the Budget proposes an expanded version of the contingency fund Congress enacted in FY 2023.
 - Unaccompanied Children: Funds would be provided if monthly arrivals exceed 10,000 in FY 2024.
 - New Arrivals: Funds would be provided if the number of Asylees and Cuban and Haitian entrants exceeds 150,000 in FY 2023 or 75,000 in FY 2024. Unlike refugees, these populations are not subject to a ceiling.

Q: Will HHS need a supplemental or be deficient before the end of FY 2023?

A: I appreciate the question. I would like to express my gratitude to Congress for providing \$10.9 billion for refugees and unaccompanied children in the FY 2023 Omnibus, \$2 billion more than the FY 2022 amount and for approving a contingency fund for Unaccompanied Children. That said, arrival numbers through February have been as high as they were in FY 2022 and the future impact of title 42 termination on referral numbers is uncertain. We will continue to assess our funding needs and operational options, and to communicate with the Congress.

Q: What is HHS doing to combat child labor exploitation among unaccompanied children?

- A:** HHS continues to work hard to protect the safety and wellbeing of unaccompanied children by providing them child-centered care while they are in our custody and follow up services after they are released. Last month, the Departments of Labor and Health and Human Services announced a series of actions to increase their efforts to thoroughly vet sponsors of migrant children, investigate child labor violations, and hold the companies accountable. HHS activities include:
- **Mandated Follow Up Calls for Unaccompanied Children Who Report Safety Concerns:** HHS will require a follow-up call to any child who calls the Office of Refugee Resettlement National Call Center with a safety concern.
 - The Center currently refers every safety related call to the appropriate law enforcement or child protective services agency.
 - This additional call will serve as a critical follow up with the child.
 - **Expand Post Release Services for Unaccompanied Children:** HHS continues to increase the percentage of children receiving services and to improve their quality.

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- HHS provided post release services to more than 40 percent of discharged children in FY 2022, nearly double the percentage receiving services when the Biden Administration took office. HHS is on track to provide services to all children who would benefit from post release services within the next two years.
- Additional post release services include assistance in registering children for school, ensuring they understand the immigration legal process and can attend their court hearings, and help finding medical, mental health, and family counseling services for which they may be eligible.
 - ACF will publish a new grant announcement this spring, expanding *eligibility* for post release services to all discharged children and establishing a new service level for specific challenges or special circumstances (e.g., medically or psychologically vulnerable children, family conflict or crisis, education-related issues).
- **Audit Sponsor Vetting Process:** HHS is auditing the vetting process for potential sponsors who have previously sponsored an unaccompanied child to ensure all necessary safeguards are in place without unnecessarily keeping children in shelter care.
 - This audit builds on steps that HHS has already taken to increase vetting of those types of sponsors and includes updates to data systems to identify such cases more easily.

Program Information

- The budget **includes \$1.7 billion to support resettlement of new arrivals.**
 - Transitional and Medical Assistance: +\$436 million above FY 2023, for a total of \$1.0 billion to provide up to 12 months of cash and medical assistance to an estimated 241,000 new arrivals (including 125,000 refugees).
 - Refugee Support Services: +\$379 million above FY 2023, for a total of \$686 million to support the increase in arrivals, and help refugees gain economic independence by helping them find and maintain employment, preferably within a year of being enrolled in the program.
- Unaccompanied Children: **\$5.5 billion**, flat with the regular FY 2023 appropriation, to **provide shelter, care, and support for all unaccompanied children.** The contingency fund will provide additional resources if needed.
 - Including FY 2023 anomaly funding, FY 2024 funding for Unaccompanied Children is \$1.4 billion less than FY 2023.
- Contingency Fund: Since the number of people needing assistance in FY 2024 can only be estimated, the budget includes \$2.8 billion for a contingency fund providing additional resources if either population exceeds anticipated levels.
 - Including the contingency fund, the Budget would support 426,000 new arrivals.
- Victims of Trafficking and Survivors of Torture: \$66 million +\$17 million over FY 2023.
 - Victims of Trafficking: +\$9 million above FY 2023, for a total of \$39 million to screen and identify trafficking victims and provide services, including case management, emergency assistance, and medical services. The hotline identified nearly 18,000 potential victims of trafficking victims in FY 2022.
 - Survivors of Torture: +\$8 million above FY 2023, for a total of \$27 million to provide rehabilitative, social, and legal services to individuals regardless of immigration status who have experienced torture that occurred outside the U.S. This program served approximately 8,400 victims of torture in FY 2022.

BACKGROUND:

- Contingency Fund for Refugees and Unaccompanied Children:
 - Current Law: FY 2023 appropriations language provides additional discretionary funds in any month when the number of unaccompanied children exceeds 13,000, +\$27 million for each increment of 500 above that level.
 - Monthly referrals exceeded 13,000 once in FY 2022 and have not yet exceeded 13,000 in FY 2023.
 - The probabilistic score of this proposal is \$326 million in FY 2023.
 - Proposed Law: The FY 2024 request includes appropriation language expanding on this proposal. Additional funds are provided if:
 - Monthly referrals of unaccompanied children exceed 10,000, +\$30 million for each increment of 500 above that level.
 - Monthly referrals have exceeded 10,000 three times so far in FY 2023.

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- Annual arrivals of Cuban/Haitian entrants and those granted asylum exceed 150,000 in FY 2023 or 75,000 in FY 2024, +\$5.5 million for each increment of 1,000.
 - Unlike refugees, these populations are not subject to a ceiling.
- Through January of FY 2023, 133,000 Cuban and Haitian entrants have entered the country and nearly 15,000 people have been granted asylum.
- The probabilistic score of this proposal is \$2.8 billion in FY 2024, \$1.8 billion for refugees and \$983 million for unaccompanied children.
- Contingency funds could be used for both refugees and unaccompanied children. They are emergency designated.
- Separated Families:
 - FY 2024 appropriations language includes a general provision, similar to the FY 2023 budget request, providing that refugee funds are available to provide mental health and other supportive services, including access to legal services, to members of families who were separated at the United States Mexico border between January 20, 2017, and January 20, 2021.
 - The Budget also includes a mandatory proposal making members of separated families eligible for public benefits (e.g., Medicaid, SNAP, SSI) to the same extent as refugees.
 - Eligibility for public benefits was included as a general provision in the FY 2023 President's Budget.
 - The budget assumes a total of 3,500 separated families would be granted parole in FY 2023 and FY 2024.

Refugees - Afghan/Ukrainian

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Transitional and Medical Services (TAMS)	564	1,000	+436
Refugee Support Services	307	686	+379
CR Emergency Supplemental	1,775	0	-1,775
Division M Supplemental	2,400	0	-2,400
Contingency Fund	326	2,776	+2,450
Trafficking Victims and	31	39	+9
Torture Survivors	19	27	+8
Total Program Level, Refugees¹	5,442	4,529	-893

¹ Excludes funds for Unaccompanied Children

TALKING POINTS:

- In the 18 months since the launch of Operation Allies' Welcome (OAW), the U.S. has welcomed approximately 94,000 individuals from Afghanistan, and over 120,000 Ukrainians are part of Uniting for Ukraine (U4U) all eligible for ORR benefits and services.
- ORR continues to fund services through the \$2.9 million ASA supplementals and a \$900 million supplemental supporting Ukrainian arrivals. These supplementals have provided cash and medical assistance, emergency housing, support for schools and enhanced mental health services.
- We are working to support longer-term housing and support legal assistance to Afghans as they pursue permanent asylee status.

Program Information

- **The budget includes – 893 million for Refugee programs. This decrease reflects – 2400M for the Division M Emergency Supplemental**
 - Transitional and Medical Assistance: +\$436 million above FY 2023, for a total of \$1B to make 12 months of cash and medical assistance available for an estimated 125,000 refugees and 116,000 other new arrivals eligible for refugee benefits.
 - Refugee Support Services: +\$379 million above FY 2023, for a total of \$686 million to support the increase in arrivals, and help refugees gain economic independence by helping them find and maintain employment, preferably within a year of being enrolled in the program.
 - Contingency Fund: Since the number of new arrivals and unaccompanied children needing assistance in FY 2024 can only be estimated, the budget includes \$2.8 billion for a contingency fund providing additional resources if either population exceeds anticipated levels.
 - Survivors of Torture: +\$8 million above FY 2023, for a total of \$27 million to provide rehabilitative, social, and legal services to individuals regardless of immigration status who have experienced torture that occurred outside the U.S. This program served approximately 8,200 victims of torture in FY 2021.
 - Victims of Trafficking: +\$9 million above FY 2023, for a total of \$39 million to screen and identify trafficking victims and provide services, including case management, emergency assistance, and medical services to an estimated 3,500 trafficking victims.

Refugees - Cuban/Haitian/Venezuelan Parole Program

TALKING POINTS:

- ORR strives to ensure equitable access to benefits and services for all ORR-eligible individuals. Cuban and Haitians coming through the new parole program are eligible for ORR services supporting their path to self-sufficiency.
 - Over 20,000 Cuban and Haitians have arrived through the new parole program.
 - The FY24 budget assumes 241,000 new arrivals eligible for refugee benefits for the year, including 116,000 non-refugee arrivals such as Cuban and Haitian entrants.
 - These individuals are eligible for ORR refugee benefits and services and are also eligible to apply for work authorization and a Social Security number.

If pushed on FY203 supplemental funding:

- ORR received \$2.4 billion in FY 2023 supplemental funding to support the impact of increased arrivals as well as unaccompanied children. ORR is working to allocate these funds to impacted areas providing cash and medical assistance and other Refugee Support Services to include employment and language supports.
 - Budgeting for these programs is challenging because the number of people they serve fluctuates. The budget request includes a contingency fund which could provide support to 426,000 new arrivals.

PROGRAM INFORMATION

- **The budget includes – 893 million for Refugee programs. This decrease reflects – 2400M for the Division M Emergency Supplemental**
 - o Transitional and Medical Assistance: +\$436 million above FY 2023, for a total of \$1B to make 12 months of cash and medical assistance available for an estimated 125,000 refugees and 116,000 other new arrivals eligible for refugee benefits.
 - o Refugee Support Services: +\$379 million above FY 2023, for a total of \$686 million to support the increase in arrivals, and help refugees gain economic independence by helping them find and maintain employment, preferably within a year of being enrolled in the program.
 - o Contingency Fund: Since the number of new arrivals and unaccompanied children needing assistance in FY 2024 can only be estimated, the budget includes \$2.8 billion for a contingency fund providing additional resources if either population exceeds anticipated levels.
 - o Survivors of Torture: +\$8 million above FY 2023, for a total of \$27 million to provide rehabilitative, social, and legal services to individuals regardless of immigration status who have experienced torture that occurred outside the U.S. This program served approximately 8,200 victims of torture in FY 2021.
 - o Victims of Trafficking: +\$9 million above FY 2023, for a total of \$39 million to screen and identify trafficking victims and provide services, including case management, emergency assistance, and medical services to an estimated 3,500 trafficking victims.
- In response to the many questions ORR was receiving from partners, grantees, and community members, ORR issued guidance clarifying that we are not authorized to provide refugee benefits and services to humanitarian parolees from Nicaragua and Venezuela, but that ORR is authorized to serve Cubans and Haitians paroled under this new supporter-based parole process.

Reproductive Health

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Title X Family Planning (HRSA Discretionary)	286	512	+226
Teen Pregnancy Prevention (GDM Discretionary)	101	111	+10
Sexual Risk Avoidance (GDM Discretionary)	35	--	-35
Embryo Adoption Awareness Campaign (GDM Discretionary)	1	1	--
Teen Pregnancy Prevention Program Evaluation (PHS Evaluation Funds)	7	8	+1
Total Program Level	430	632	+202

TALKING POINTS:

- Since Title X was created, **more than 195 million predominantly low-income clients** have received quality healthcare through Title X as their usual source of medical care, including the services, information, and referrals, that higher-income clients and clients with private insurance get.
- 3,284 community-based sites have provided clinical and educational services to **over 1.7 million persons** in 2021 (most recent year available) through 2.8 million family planning encounters.
- Title X has long been the gold standard of family planning care, and this administration has re-doubled its **emphasis on quality by realigning the program's requirements with national clinical recommendations** on delivering quality family planning services.
- Title X offered cervical and breast cancer screening services to over 320,000 female users and funds sexually transmitted disease and HIV testing for preventing disease transmission and adverse health consequences.
- In 2021, 86% of clients had family incomes at or below 250% of the FPL, and 65% of all clients were entitled to free services with incomes at or below 100% FPL.

QUESTIONS:

Q: Why is the Sexual Risk Avoidance program being eliminated in FY24?

A: Proponents of adolescent health, including prevention of teenage pregnancy, strongly oppose this program because of the lack of evidence that it works and have expressed concern that it could rather have adverse impact on overall teenage health and behavior. The FY24 budget shifts this funding into the evidence-based Teen Pregnancy Prevention program and Title X Family Planning program, continuing support for vulnerable populations with proven and effective programming.

Q: Will these funds be used to provide abortion services?

A: The Title X program does not provide abortion services. Section 1008 of the Public Health Service Act specifically states that “None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.” Consistent with the program’s statute and regulations, any public or private nonprofit organizations, including faith-based organizations, state, county, local, and tribal governments, school districts, and public and state higher education institutions are eligible to apply for Title X grant funds. Title X’s regulations also clearly define the criteria the Department uses to decide which family planning services projects to fund and in what amount.

Q: The 2021 Title X final rule argued that it was necessary to restore and expand access to Title X family planning services. Has the administration succeeded in getting new providers and what is the impact on funding for loyal family planning grantees that did not leave the program since there was no increase in funding?

A: The demand for Title X funding for highly qualified providers to deliver care in communities far exceeds the resources available.

- A federal study from 2016 estimated that Title X would need \$737 million to serve just all of the women in need of Title X care.
- The reality is that it has been eight years since there was an increase for Title X through the annual appropriations process.
- As a result, the Department has had to make tough choices with a focus on ensuring that as many clients in as many communities can get the quality family planning care they want and need.

Q: What is HHS doing to protect individual’s rights to reproductive care as we see attacks across the country?

A:

- HHS has taken several meaningful actions under the Biden-Harris Administration to protect and bolster reproductive health, rights, and justice.
- In October 2021, we issued a final rule for the nation’s family planning program to strengthen access to equitable, affordable, client-centered, and high-quality family planning services nationwide.
- In January 2022, we announced \$6.6 million for the Title X planning program to address demand for family planning services where restrictive laws and policies have impacted reproductive health access.

Q: Maternal Mortality surged by nearly 20% during the first year of COVID-19 (2020), and the gap between black and white maternal mortality grew. What is HHS doing to reduce these disparities and address this maternal crisis in the US?

A:

- This is a key priority for me personally and the Biden-Harris Administration.
- Thanks to the American Rescue Plan, we have worked with states to expand Medicaid coverage of postpartum health care for 12 months. Illinois, Georgia, Missouri, New Jersey and Virginia have led this important initiative.
- We increased funding for Enhancing Reviews and Surveillance to Eliminate Maternal Mortality Program to reach six additional states, for a total of 30 awards supporting 31 states. This funding directly supports agencies and organizations that coordinate and manage Maternal Mortality Review Committees (MMRCs) to identify, review, and characterize pregnancy-related deaths; and identify prevention opportunities.

The 2021 Title X final rule revoked requirements of the 2019 regulations, including removing restrictions on nondirective options counseling and referrals for abortion services and eliminating requirements for strict physical and financial separation between abortion-related activities and Title X project activities. Will this change lead to use of federal funds to pay for or promote abortion services?

- The 2019 Trump Administration regulations substantially diminished the Title X family planning network by forcing requirements inconsistent with nationally recognized clinical recommendations. The impact of both the Trump Administration's regulations and the pandemic led to a drop in the number of clients served from 3.9 million to 1.5 million people. The new regulations restore many aspects of the program that were removed through the Trump administration regulations.
- The final Biden Administration Title X regulations allows all highly qualified family planning providers, including clinics like Planned Parenthood that provide abortion services outside of Title X with non-federal funds, to once again apply for federal support to provide family planning services to low-income and uninsured individuals.
- Advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, is a priority for the Administration, including the Title X program and the Department. This 2021 regulation will allow for the Title X service network to expand in size and capacity to provide quality family planning services to more clients.
- As outlined by the Title X statute and reinforced in its regulations, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." Consistent with the program's statute and regulations, any public or private nonprofit organizations, including faith-based organizations, state, county, local, and tribal governments, school districts, and public and state higher education institutions are eligible to apply for Title X grant funds. Title X's regulations also clearly define the criteria the Department uses to decide which family planning services projects to fund and in what amount.

Q: ReproductiveRights.gov provides information to the public, including young people, on where to access an abortion. Why are federal funds going to promote and facilitate abortion access? How will HHS budget be used this year to continue to promote this website?

A:

- HHS created reproductiveRights.gov to be an easily accessible online portal for people to access information regarding where to access the full range of reproductive health care services and rights associated with these services.
- This website links to a variety of trusted resources regarding reproductive health care services.
- HHS will continue to serve as a trusted resource for information, particularly given the range of misinformation, confusion, outright false information that continues to be available on the internet given the shifting legal landscape around reproductive rights.
- HHS will always follow the law when it comes to federal spending.

Program Information

- **The Budget supports reproductive health through increases to the Title X Family Planning and Teen Pregnancy Prevention programs:**
 - Title X Family Planning: +\$226 million above FY 2023, for a total of \$512 million, through competitive grants to assist individuals and families in determining the number and spacing of children and to provide access to voluntary family planning methods, services, and information to all who want and need them.
 - Services include fertility awareness-based methods, infertility services and services for adolescents.
 - Funds will also support demonstration grants to test innovative approaches to family planning service delivery that build on national efforts to achieve health equity and improve health outcomes for medically underserved populations.
 - Teen Pregnancy Prevention: +\$10 million above FY 2023, for a total of \$111 million to support community efforts to reduce teen pregnancy through grants to replicate programs that have been proven effective, and an embryo adoption campaign.
 - Sexual Risk Avoidance: Eliminates the Sexual Risk Avoidance program, -\$35 million below FY 2023, in favor of increasing investments in Teen Pregnancy Prevention and Title X Family Planning programs.

Return to Work

TALKING POINTS:

- The COVID-19 pandemic reshaped the workplace for many Americans, including federal employees at HHS.
- While COVID-19 is no longer a determining factor for how we do our work, the pandemic has forever changed both the public and private sectors' approaches to the way work is done. Hybrid work environments have allowed federal agencies, including HHS, to stay competitive with other sectors, ensuring we are recruiting and retaining the best talent to help meet the needs of the American people.
- Federal agencies, including HHS, are strategically using personnel policies like telework, remote work, and flexible work schedules to advance their missions and better compete in the national labor market to attract and retain a well-qualified and engaged federal workforce.

QUESTIONS:

Q: How many days were you personally in the office last week?

I can assure you that this is a 24/7 job and I treat it as such, whether I am in the office or on the road helping advocate and elevate the work of HHS and our incredible divisions.

Q: In last year's SOTU, President Biden said "the vast majority of federal workers will once again work in person." Yes or no, are the vast majority of your employees working fulltime in person today?

- Our employees are working fulltime.
- HHS is unique in that the Department has thousands of mission critical employees who never left their worksites, even at the height of the COVID-19 pandemic. Together with those employees working remotely, HHS continues to meet its mission for the American public.
- Some individuals are on-site full-time, the majority of the workforce reports to their workplace every pay period, and some workers are fully remote. Regardless of an employee's physical location, they continue to work hard every day to carry out the mission of HHS.
- I would also note that we have scientists in labs and service providers in the field working hard every day who may or may not be regularly logging into systems, depending on their work's needs.
- *If pressed on numbers:* I do not have those numbers on hand and would note this is not a static situation.

Q: Do you believe HHS's mission is hindered by having so many employees working remotely?

- In just the last two years, HHS and its operating divisions have accomplished incredible work for the American people, including:
 - The roll-out and distribution of 294 million vaccines doses to 75,000 sites across the country as well as 670 million at-home COVID-19 test kits-.
 - The largest and most successful open enrollment to date in 2022 with 14.5 million people signed up for or enrolled in Marketplace coverage.
 - Increased provider access to buprenorphine, the medication assisted treatment for opioid use disorder, by 21% from 2021 to 2022.
 - Transition to the 988-suicide prevention lifeline – an easy-to-remember number for 24/7 crisis care.
- All these accomplishments, which are just a snapshot of HHS' work, occurred while the agency offered a telework or hybrid posture for some employees. These milestones reflect how the Department continues to deliver for the American people and promote the health and well-being of the nation.

Rural Health

	FY 2023	FY 2024	
	Enacted	President's Budget	+/- FY 2023 Enacted
Rural Health Policy Development	11,076	11,076	-
Rural Health Outreach Grants	92,975	95,375	+2,400
Rural Hospital Flexibility Grants	64,277	64,277	-
State Offices of Rural Health	12,500	12,500	-
Radiation Exposure Screening and Education Program	1,889	2,734	+845
Black Lung	12,190	12,190	-
Rural Communities Opioid Response	145,000	165,000	+20,000
Rural Residency Planning and Development	12,500	12,700	+200
Rural Health Clinic Behavioral Health Initiative	-	10,000	+10,000
Financial and Community Sustainability for At-Risk Rural Hospitals	-	10,000	+10,000
The Rural Hospital Stabilization Pilot Program	-	20,000	+20,000
Subtotal, Federal Office of Rural Health Policy	352,407	415,852	+63,445

TALKING POINTS:

- Health care should be accessible, no matter where you live.
- The Biden-Harris Administration is dedicated to improving access to health care in rural communities and addressing the issues which contribute to health inequities impacting these communities.
- Thanks to Congress's leadership in the Consolidated Appropriations Act of 2021, CMS has implemented a new Medicare provider type, the Rural Emergency Hospital. Applications are available now for hospitals in rural areas that would like to change to this new provider type.
- Over the last two years, through the Rural Communities Opioid Response (RCORP) program, we have served over two million rural individuals.
- The President's Budget seeks to support and expand these programs to ensure every person has the same level of care no matter their zip code.

QUESTIONS:

Q: We have seen large increases in costs for hospitals, including labor costs. Are you aware of this issue, and do you believe it may be time to update the method for reimbursing hospital labor costs to better reflect new staffing practices?

- HHS is committed to promoting Medicare payment accuracy and hospital stability.
- In computing the Hospital Wage Index, CMS follows a process established by law. In applying the law, CMS strives to ensure access for all beneficiaries while maintaining incentives for the agency's hospital partners to operate efficiently.
- The goal of the hospital wage index is to adjust hospital payment rates to account for local differences in the wages.

Q: Which telehealth services will no longer be covered under Medicare after the public health emergency is over?

- Thanks to the Consolidated Appropriations Act of 2023, many telehealth flexibilities available during the public health emergency have been extended through December 31, 2024.
- *If needed:* I would be happy to have my colleagues in CMS follow up with you on questions about specific waivers.
- For over 36 years, HHS has played a leading role in improving the health and well-being of rural Americans.
- HHS funds a range of programs that directly support rural communities to increase access to care in rural communities, build the infrastructure necessary to implement the services, and train and expand the workforce in rural communities.
- Additionally, HHS supports the only federal research program specifically focused on rural health issues.
- Our Budget requests a \$63 million increase for rural programs, which is critical amid ongoing challenges of health care access and disparities.

Q: How does HHS plan to utilize the requested budget increase for rural health programs?

- HHS is requesting \$20 million to continue to support substance use disorder prevention and treatment in rural communities including the creation of new medication assisted treatment access points and equipping first responders with naloxone.
 - The Rural Communities Opioids Response program funds prevention, treatment, and recovery services in rural communities, serving over two million rural individuals between 2021 and 2022.
 - We plan to reach even more rural individuals with this increased funding.
- In addition, we are requesting \$40 million for three new programs to meet the unique health needs of rural communities as they face hospital closures and service reductions exacerbating disparities in access to care.
 - \$10 million for the Rural Health Clinic Behavioral Health Initiative which aims to expand access to behavioral health care services at Rural Health Clinics;

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- o \$10 million for Financial and Community Sustainability for At-Risk Rural Hospitals which targets technical assistance to rural hospitals at-risk for closure; and
- o \$20 million for the Rural Hospital Stabilization Pilot Program to enable at-risk hospitals to expand their services, such as obstetric services, chemotherapy, and more, to create new care in the community while expanding revenue streams to stabilize operations and meet local needs.

Program Information

Hospital Wage Index

- The Social Security Act requires that, as part of the methodology for determining prospective payments to hospitals, the standardized amounts for area differences in hospital wage levels are adjusted by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. This adjustment factor is the wage index, which must be updated annually, based on a survey of wages and wage-related costs of short-term, acute care hospitals. Data included in the wage index derive from the Medicare Cost Report, the Hospital Wage Index Occupational Mix Survey, hospitals' payroll records, contracts, and other wage-related documentation.

Rural Emergency Hospitals (REHs)

- The Consolidated Appropriations Act of 2021 established Rural Emergency Hospitals (REHs) as a new Medicare provider type to address the growing concern over closures of rural hospitals. The REH designation provides an opportunity for Critical Access Hospitals and certain rural hospitals that generally do not provide acute care inpatient services to avert potential closure. By converting to an REH, eligible rural facilities are able to provide emergency services, observation care, and additional medical and health outpatient services. In January 2023, CMS issued guidance regarding the REH enrollment and conversion process for eligible facilities. Some hospitals have already converted to this new provider type in 2023.

Expanding Access to Behavioral Health Care in Rural Communities

- Rural communities have been particularly hard hit by the opioid epidemic, and FORHP works to address substance abuse and mental health issues through programs and initiatives that focus on prevention, treatment, and recovery.
- FORHP's Rural Communities Opioid Response Program works to strengthen capacity of rural communities to plan for, and provide, behavioral health care services, including mental health and opioid and substance use disorder (OUD/SUD) prevention, treatment, and recovery services.
- Rural Communities Opioid Response Program funding has reached approximately 1,800 counties across 47 states and two territories.
- In FY 2023, HHS piloted new programs that provided funds to rural communities to rapidly address their immediate SUD needs (including lifesaving naloxone).
- They also provided needed prevention, treatment, and recovery services to rural residents, including for children and adolescents, and pregnant and postpartum people.

Shortages/Supply Chain Issues

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	10	22	+12

¹ Funding is specific to continue building capabilities for the supply chain and shortages program for medical devices.

TALKING POINTS:

- We continue to take steps to closely monitor the supply chain and address shortages to help protect Americans' access to critical medical products. As you know FDA is limited in it's authorities to prevent and resolve shortages.
- Right now the FDA can:
 - Assist with production by expediting reviews of new marketing submissions, production lines, or material sources to increase production;
 - Extend Product expiration dates by reviewing requests for extensions of product expiration dating; and
 - And exercising temporary regulatory flexibility and discretion.
- The budget invests **\$26 million** in ongoing efforts to modernize the agency's safety surveillance and oversight program, mitigate supply chain interruptions, and enhance active surveillance system for medical devices.

We are also requesting important new authorities to enhance FDA's ability to forecast, prevent and resolve the supply chain challenges. Such as a requirement for manufacturers to alert FDA when there is an increase in demand of a product, as we saw this past year.

QUESTIONS:

Q: How does the Agency prevent or respond to drug shortages?

- As a result of presidential, congressional, and FDA actions, drug manufacturers are notifying FDA earlier than in the past about certain manufacturing interruptions and discontinuances.
- These early notifications give FDA additional time to work with manufacturers and other stakeholders to identify ways to maintain treatment options and prevent or mitigate a shortage.
- FDA helps prevent and resolve drug shortages in various ways such as: expediting reviews of new production lines or material sources to increase production; reviewing requests for extensions of product expiration dating; and exercising temporary regulatory flexibility and discretion.

- FDA has been able to help prevent shortages, but we are seeing continued challenges and hearing from manufacturers frequently about potential disruptions in their supply and from patients who cannot find the medical products they need.
 - Manufacturers are not expressly required to notify FDA when a shortage is due to increased demand.
 - Having early indication of increases in demand may allow the Agency to better utilize our authorities associated with drug shortages and work with manufacturers to help avoid unnecessary drug shortages driven by demand.
 - Many underlying causes of shortages are likely related to economic/market forces that go beyond a regulatory agency's jurisdiction. FDA cannot order manufacturers to continue making a product or to make more of the product. Nor can FDA tell them how to distribute their products.

Q: How does the Agency prevent or respond to device shortages?

- FDA's authorities for medical device shortages remain limited.
- As a result of the CARES Act of 2020, manufacturers of critical devices have, during the COVID-19 public health emergency, been notifying FDA about certain manufacturing interruptions and discontinuances.
 - These notifications have given FDA more timely information to work proactively with manufacturers and other stakeholders to identify alternative sources of raw materials and device components and work through other supply chain issues.
- FDA helps prevent and mitigate device shortages in various ways such as: expediting reviews of new marketing submissions, expediting inspections, granting emergency use authorizations, and exercising temporary regulatory flexibility
- During the public health emergency, FDA used the information we collected under these new authorities to help prevent or mitigate approximately 350 of the 455 device shortages or potential shortages that emerged.
 - Unfortunately, FDA's authority to require notifications from manufacturers of critical medical devices is temporally limited to "during or in advance of" a public health emergency, and will lapse when the public health emergency declaration expires.
 - COVID-19 also showed us that manufacturers are not always prepared for situations where their ability to manufacture product may be disrupted or may be insufficient to meet increases in demand. Providing FDA clear authority to review risk management plans (RMPs) would help ensure resiliency and mitigate future supply chain disruptions.

State Opioid Response (SOR) Grants

TALKING POINTS:

- Since the State Opioid Response (SOR) program began, approximately 1,148,900 patients have received treatment services, including almost 553,350 who have received an FDA-approved medication for opioid use disorder.
- The budget provides \$5.7 billion for SAMHSA's substance use prevention and treatment activities, an increase of \$1.3 billion over FY 2023 enacted, funding states and territories to increase access to treatment for substance use disorder, advance public-health interventions like naloxone, and expand recovery support services.
- The budget request for the SOR program at the FY 2024 budget level (\$2 billion) would enhance states' ability to address opioids and stimulants and respond to the overdose epidemic that have been exacerbated due to the COVID-19 pandemic.
- We understand the importance of avoiding funding cliffs across all states as we develop the next iteration of the formula. Ultimately, we want to help states address their needs.

QUESTIONS:

Q: Overdoses continue to skyrocket. Can you please explain what the State Opioid Response funds are used for and any accomplishments from last year?

- The SOR program provides funding to states and territories to implement strategies that prevent, intervene in, and promote recovery from issues related to opioid use and misuse and stimulant use.
- In FY 2022, SAMHSA awarded base State Opioid Response grants to 58 states and territories via a formula. The program includes a 15 percent set-aside for states with the highest mortality rate related to drug overdose deaths.
- Since the program began, states report that approximately 1,148,915 patients have received treatment services, including 553,347 who have received an FDA-approved medication for opioid use disorder.
- Through the program, 97,768 patients received treatment services for stimulant use disorder and 1,171,670 patients received recovery support services.
- It is also important to note that SAMHSA also provides Tribal Opioid Response grants through this program, which addresses the public health crisis of escalating opioid misuse and overdose in Tribal communities. In FY 2022, SAMHSA awarded \$55 million in TOR grants.
 - Since 2018, Tribes and Tribal organizations have provided TOR-funded treatment and recovery support services to 7,700 clients. Tribes have also purchased and distributed 16,955 naloxone kits and 7,045 fentanyl testing strips and trained 3,357 community members on the use of lifesaving naloxone.

Q: As you work to administer State Opioid Response grants this year, will you commit to working with me to ensure that small changes in a state's ranking in opioid overdose deaths do not result in large-scale reductions in funding?

- The State Opioid Response Grant program is a critical program helping states address the overdose epidemic. For the FY 2022 and FY 2023 SOR awards, SAMHSA held states harmless for pandemic-related factors and a data definitional change for substance use disorders that occurred in 2020.
- We understand the importance of avoiding funding cliffs across all states as we develop the next iteration of the formula. Ultimately, we want to help states address their needs.

Q. Fatal and non-fatal overdoses on Native American Reservations are typically higher, can you share any data on what the Tribal Opioid Response (TOR) grants were used for last year?

- In FY 2022, SAMSHA funded 102 new Tribal Opioid Response grants. Since 2018, Tribes and Tribal organizations have provided Tribal Opioid Response-funded treatment and recovery support services to 7,700 clients.
- Tribes have also purchased and distributed 16,955 naloxone kits and 7,045 fentanyl testing strips and trained 3,357 community members on the use of lifesaving naloxone.
- Tribes and Tribal organizations funded through TOR also educated over 25,000 individuals on the consequences of opioid misuse and overdose through prevention activities.

Program Information

The State Opioid Response Grants (SOR) program was established by Congress in 2018 through the 21st Century Cures Act to address the public health crisis caused by escalating opioid misuse and substance use disorder across the nation. CDC provisional data indicate there were 107,477 predicted drug overdose deaths in the United States during the 12-month period ending in August 2022, an increase of 3.3 percent from the 104,038 predicted deaths during the same period the year before.² In addition, there were an estimated 76,683 drug overdose deaths involving opioids for the 12-month period ending in August 2022, a decrease of 0.49 percent from the 77,060 opioid-involved drug overdose deaths reported during the same period the year before. Illicitly manufactured fentanyl continues to drive the majority of deaths, but mortality rates due to cocaine and psychostimulants such as methamphetamine have also increased, both with and without the presence of fentanyl. As in other areas, the COVID-19 years saw an exacerbation of health disparities in overdoses.

The SOR program provides resources to states and territories to continue and enhance the development of comprehensive strategies focused upon preventing, intervening, and promoting recovery from issues related to opioid use and misuse and stimulant misuse. This program aims to address the overdose crisis by increasing access to the three FDA-approved medications for the treatment of opioid use disorder (MOUD), reducing unmet treatment need, and reducing opioid-related overdose deaths through the provision of prevention, public health harm reduction interventions, treatment, and recovery activities for opioid use disorder (OUD) and other concurrent substance use disorders. The SOR program also supports the continuum of care for stimulant misuse and use disorders, including for cocaine and methamphetamine. In FY 2022, SAMHSA awarded base grants to 58 states and territories via a formula. In addition, the program includes a 15 percent set-aside for states with the highest mortality rate related to drug overdose deaths.

The SOR program requires grantees to use evidence-based treatments, practices, and interventions for OUD and stimulant use disorders. The program requires that MOUD is available to those diagnosed with OUD. MOUD includes methadone, buprenorphine products, including single-entity buprenorphine products, buprenorphine/naloxone tablets, films, long-acting injectable buprenorphine products and injectable extended-release naltrexone. The program supplements activities pertaining to opioids currently undertaken by the state agency that also manages the Substance Use Prevention, Treatment, and Recovery Services Block Grant, and supports a comprehensive response to the overdose epidemic. The program identifies gaps and resources, while building upon existing substance use primary prevention, public health harm reduction interventions including naloxone and fentanyl test strip purchase and distribution, and treatment activities as well as community-based recovery support services. A primary strategy to reduce overdose deaths in the SOR program, that will continue in FY 2024, is education on, and purchase and distribution of, naloxone, a proven medication that reverses opioid-related overdoses to save lives.

In addition to the grant program, SAMHSA supports a robust technical assistance and training effort to enhance education across the country to address the overdose crisis. This effort is available not only to SOR and Tribal Opioid Response grantees but to all their sub-recipients and affiliated entities. A key component of this technical assistance is local teams of multi-disciplinary experts, including clinicians, preventionists, and recovery specialists, in every state. These teams and the technical expertise and educational resources provide training not only to individual practitioners but also to individuals and families, healthcare practices, and law enforcement, criminal justice groups, and other community-based organizations. Providing this training ensures that local response to the opioid and overdose crisis is tailored to local needs.

Tribal Opioid Response Grants

The Tribal Opioid Response Grants (TOR) is a key component of the SOR program and seeks to address the public health crisis of escalating opioid misuse and overdose in Tribal communities. The purpose of the TOR program is to assist in addressing the overdose crisis in Tribal communities by increasing access to FDA-approved medications for the treatment of opioid use disorder (MOUD), and supporting the continuum of prevention, public health harm reduction interventions, treatment, and recovery support services for opioid use disorder (OUD) and co-occurring substance use disorders. The TOR program also supports the full continuum of prevention, public health harm reduction, treatment and recovery support services for stimulant misuse and use disorders, including for cocaine and methamphetamine. According to the Centers for Disease Control and Prevention, American Indians and Alaska Natives (AI/AN) had the highest drug overdose death rates in both 2020 and 2021.

American Indian and Alaska Native communities experience high rates of physical, emotional, and historical trauma and significant socioeconomic disparities, all of which may contribute to higher rates of drug misuse in the Tribal communities.^[1] The TOR program addresses the gaps in prevention, public health harm reduction, treatment, and recovery identified by Tribes and supports strategies to purchase and disseminate naloxone and provide training on its use to first responders and other Tribal members.

[1]

https://www.cdc.gov/injury/tribal/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Finjury%2Ffundedprograms%2Ftribal.html

Surprise Billing

TALKING POINTS:

- I would like to start by again thanking Congress for its leadership in enacting this law to protect patients from surprise billing in health care. Patients and their families deserve the security of knowing they are kept out of the middle of disagreements between insurers and providers. HHS—together with our colleagues at the Department of Labor, Department of the Treasury, and Office of Personnel Management—has been working to implement the No Surprises Act and ensure that consumers receive the benefits of the protections included in the law by Congress.
- We are committed to continuing to protect patients from crippling medical bills and increase transparency in our health care system. That is why this Administration is requesting \$500 million to replenish and extend the No Surprises Act Implementation Fund.

If pressed on the current status:

- Because of a recent court order, IDR entities are holding issuance of payment determinations that involve items or services delivered **on or after October 25, 2022** until the Departments issues further guidance.
- The Departments are working diligently to complete necessary guidance and system updates in order to allow certified IDR entities to resume processing payment determinations for these disputes.
- Disputes involving items or services furnished **before October 25, 2022** are proceeding.

QUESTIONS:

Q: There is concern about the provider burden and impact of an increased administrative fee. Can you give additional detail on the methodology and rationale for the administrative fee increase?

- As you know, we released an initial public report on the Federal IDR process and an updated administrative fee guidance document for 2023. There are two big trends.
 1. First, there is a very high volume of disputes being submitted for resolution, significantly more than we or the IDR entities anticipated or were staffed for. For example, through December 5th of last year, there were over 160,000 disputes submitted through the portal.
 2. Second, IDR entities have had to perform a substantial amount of outreach and analysis to determine whether a dispute is eligible for the Federal IDR process.
- The high volume and complexity of this work was taking away from IDR entities' ability to review bona fide disputes and the structure of the No Surprises Act regulations prevents IDR entities from being compensated for cases that are not eligible.
- We've taken steps to help address some of the ongoing challenges created by the large initial volume of disputes to allow IDR to focus on making payment determinations, including making sure the administrative fee covers "pre-eligibility" actions and setting that fee at a level that covers the estimated annual cost of operating the Federal IDR

process and working on system changes and considering policy options that will allow us to reduce the IDR administrative fee in the future and make the process smoother for everyone.

Q: Why is the Administration requesting additional funds for No Surprises Act implementation?

- To implement the No Surprises Act, the Departments scaled up expertise and resources for rulemaking, technical builds, enforcement, and staffing.
- A one-time lump-sum appropriation of \$500 million was provided to the Departments for implementation of the No Surprises Act and Title II Transparency provisions.
- While the original appropriation expires at the end of 2024, most of the statutory requirements added by the No Surprises Act and Title II Transparency provisions are permanent and the Departments will have ongoing responsibilities such as enforcement of plan, issuer, and provider compliance; complaints collection and investigation; as well as auditing comparative analyses of non-quantitative treatment limits for mental health and substance-use disorder plan benefits.
- While some activities, particularly those around the Federal IDR process, are supported through a separate administrative fee, many other activities implementing the No Surprises Act are not.
- Factoring in cost projections for those activities that the Departments are currently undertaking, the Departments project that the No Surprises Act Implementation Fund will be exhausted before the end of calendar year 2024. The continued implementation of these provisions will have to compete against other agency priorities and initiatives, especially as funding for certain appropriations, such as for CMS Program Management, haven't kept pace with the increasing responsibilities that have been delegated to the agencies.

Q: A recent article suggests that there may be a loophole in the No Surprises Act allowing providers to remain out-of-network while contracting with plans as a 'participating' provider, thereby exposing patients to out-of-network coinsurances for services, including when they have not received notice or provided consent to those services or charges. What is HHS doing to evaluate this potential loophole and ensure that it is not impacting patients?

- Patients and their families deserve the security of knowing that their coverage will be there for them when they need it. We are investigating the issues raised in the article. We take seriously the effective implementation of the law as intended to protect consumers from surprise medical bills, and we value your feedback as we do so.

Q: We have heard from stakeholders that payments to the winning party in an IDR dispute are not being made in a timely manner in accordance with the requirements of the No Surprises Act. What is HHS doing to enforce the requirement that any payment owed by a health plan or provider as a result of an IDR decision is being made promptly?

- Our regulations require that the losing party remit payment within 30 days of a payment determination. If the prevailing party believes that the non-prevailing party isn't complying with the payment requirements with the dispute resolution process, then we encourage them to contact the No Surprises Help Desk to submit a complaint.
- We are investigating the complaints that we have received on this issue.

Q: Does CMS intend to release the findings of their Qualifying Payment Amount (QPA) audits, in addition to submitting a report on these audits to Congress as required by the No Surprises Act?

- We are conducting qualifying payment amount (QPA) audits to ensure that plans are complying with requirements related to its calculation and disclosure.
- The Departments are actively conducting QPA audits as required under the statute and intend to produce the reports to Congress required.

TANF

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Mandatory Program Funding	17.3B	17.3B	
Proposal Impact to TANF	-	5	5
Proposal Impact to TANF Contingency Fund	-	(5)	(5)
Total Program Level	17.3B	17.3B	-

TALKING POINTS:

- The Department shares your commitment to an effective safety net system that ensures funds are spent to accomplish a TANF purpose and welcomes the opportunity to work with you to strengthen TANF.
- TANF is intended to serve as a critical support to families experiencing economic hardships, providing cash assistance, employment and training assistance, and related services to ensure families can meet basic needs, get access to opportunities in the job market, and remain together; and we must strengthen the program so that it can meet its purposes and continue to support families and communities.
- We will continue to support all grantees in strengthening policies and practices that effectively invest in basic assistance and family supports with program integrity and accountability.
 - The Department is requesting new statutory authority in the TANF program to increase transparency with respect to TANF spending and implement program integrity measurement across the program.
 - Increased monitoring of TANF expenditures and their alignment with allowable uses of block grant funds are necessary to ensure that TANF functions as it was intended – as a critical support to families experiencing economic hardships, providing cash assistance, employment and training assistance, and related services so that families can meet basic needs, get access to opportunities in the job market, and remain together. ACF wants to collect data to improve monitoring of allowable uses of funds.
 - Congressional action is needed to equip the Department to fully implement additional program integrity measures. We welcome the Committee’s partnership in supporting these requests.

QUESTIONS:

Q: Mississippi has been in the news for the large-scale conspiracy and embezzlement of millions of dollars in TANF funding involving the Mississippi Department of Human Services. How are largescale abuses like this happening under HHS' watch?

- As has been reported in the news media, multiple Federal and State agencies are continuing to review this case.
- While we are unable to share specifics on the ongoing assessment of misuse of funds in Mississippi, we do want to reaffirm our commitment to ensuring the highest degree of accountability and integrity within the TANF program nationally.

Q: What is the Department doing to recover taxpayer dollars?

- The Department will work to recover any misused TANF funds from the state. Federal law requires that a state replace with its own state funds any federal TANF funds subject to penalty because the funds were misused.
- When the Department has a complete assessment of the extent of the fraud and misuse, we intend to pursue all appropriate measures, including a TANF penalty, if warranted. The Department does not recover funds directly from individuals or a state's subgrantees.

Q: The Mississippi case demonstrates that state misuse of TANF funds is rampant. Can you speak to how the program has strayed from Congressional intent? Has HHS conducted a systematic review to identify areas of fiscal, administrative, or programmatic weaknesses in the TANF program?

- More than 26 years since TANF was established, state programs have shifted away from a focus on direct cash and employment assistance—services we know make the biggest impact on reducing family and child poverty and are reaching the fewest number of families since passage of welfare reform.
- At the same time, states are using TANF funds on a wide range of benefits and services that have tenuous connection to the statutory purposes of TANF and Congressional intent, including funding for activities without regard to the income or parental status of the recipient.
- HHS has limited oversight of state TANF programs. When possible, HHS uses existing tools to oversee the program, such as Single Audit Reports and other reporting mechanisms. HHS has conducted periodic improper payment risk assessments and works to address weaknesses identified as part of that process (as well as through other oversight mechanisms).
- We intend to pursue all options within our authority to ensure allowable expenses align with TANF purposes.

Q: Has HHS conducted a systematic review to identify areas of fiscal, administrative, or programmatic weaknesses in the TANF program?

- Due to statutory limitations on information that HHS is able to collect from states, the Single Audit report is a key oversight and monitoring tool for the TANF program. Single Audits assess if states have complied with program requirements for areas including

allowable activities, allowable costs, cash management, eligibility, reporting, period of availability of funds, procurement, and sub-recipient monitoring.

- ACF staff thoroughly review the Single Audit reports to determine the need to assess any TANF penalties, as required by statute, as well as to identify areas where states may need additional supports and technical assistance to remediate any weaknesses in internal controls.
- HHS has also completed a TANF improper payment risk assessment, which is used to identify areas of additional risk mitigation.

Q: Does the Department have processes in place to measure and report the amount of improper payments in the TANF program?

- Statutory limitations preclude HHS from collecting information needed to calculate and report a national TANF improper payment error rate.
- This constraint significantly limits ACF's ability to request data needed to calculate a national error rate.
- However, the proposal included in the FY 2024 President's Budget Request, if enacted, would allow ACF to collect data elements pertaining to a range of TANF expenditures, including subrecipient payments for benefits and services, and allow the agency to calculate and report a more robust national TANF error rate estimate.

Program Information

BACKGROUND:

Ways and Means Republicans sent a letter at the end of the 117th Congress requesting information on HHS oversight actions and efforts to promote accountability and safeguard funding in the TANF program.

TANF was designed to provide states with flexibility while requiring them to engage recipients in work activities. TANF provides states, territories, and eligible tribes the opportunity to design programs funding a wide range of services that support children and families in alignment with the program's purposes, which include providing assistance so that children may be cared for in their own homes or with relatives, promoting job preparation, work, and the formation and maintenance of two-parent families. States may transfer a portion of their TAND grant to the CCDBG program and the Social Services Block Grant program, increasing the program's flexibility.

The TANF contingency Fund provides additional assistance to states that meet certain economic criteria such as high unemployment. Spending is capped at \$608 million per year, but actual outlays vary based on economic conditions.

Title 42

TALKING POINTS:

- Title 42 permits the Director of the CDC to prohibit the introduction of persons when there is serious danger of the introduction of a communicable disease into the United States—and also to aid in continued efforts to mitigate spread of that disease.
- Based on the latest public health information at the time, CDC terminated all Title 42 orders in April 2022.
- However, as you know, the Title 42 Order remains in place due to court order.
- The public health system whether through Title 42 or any other measure is not a replacement for meaningful immigration reform, and it is incumbent upon Congress to come together and find a comprehensive solution.

QUESTIONS:

[Defer questions on DHS readiness to DHS]

Why is the Department not using Title 42 to stop Fentanyl from coming across the border?

- The authority under Title 42 is rooted in protecting public health in regard to communicable disease.
- While the public health emergency for the opioid crisis is ongoing and we have grave concerns about the increase in overdoses, drug interdiction, drug trafficking, and drug use are outside the scope of Title 42.

Tobacco

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Tobacco User Fees	712	812	+100

TALKING POINTS:

- HHS and FDA are laser focused on protecting children from the harms of tobacco use. Since 2019, e-cigarette use among youth has been **reduced by almost 50 percent**.
- FDA has taken significant enforcement actions against e-cigarette companies in the last year, issuing taken action on **99% of the 26 million** e-cigarette product applications. FDA has issued over **1.2 million market denial orders**, and for the first time ever issued civil monetary penalties against e-cigarette companies in violation of the law.
- The Budget provides \$780 million in tobacco user fees to invest in product review and evaluation, research, compliance and enforcement, public education campaigns, and policy development.
- To enhance the regulation of these products and to better protect our children, the budget proposes an additional **\$100 million** in tobacco **user fees**, and provides FDA with the authority to assess user fees from manufacturers and importers of all deemed products.
- This investment will support **Center for Tobacco Product's five-year strategic plan** and comprehensive policy agenda; optimize the application review framework; support additional action to remove illegal products from the market; and enhance public communications and transparency around our work.

QUESTIONS:

Q: How will FDA improve consistent regulation of the tobacco industry?

- We've made important progress and reached science-based regulatory decisions across a broad array of products in the 13 years since Congress tasked the FDA with regulating tobacco products.
- And yet, while the current cigarette smoking rate is the lowest in history, we are faced with significant challenges because of the evolving use of tobacco products, especially in the e-cigarette industry.
- FDA plans to release a five-year strategic plan and comprehensive policy agenda; optimize the application review framework; take additional action to remove illegal products from the market; and enhance public communications and transparency around our work.

Internal Use Only – U.S. Department of Health and Human Services

- It's imperative that we are able to meaningfully implement transformational regulations and make decisions based on the public health standard in the law, with the American public – not the interests of the tobacco industry – at the forefront.
- These efforts could be bolstered by the budget proposal to increase user fee collections by \$100 million, which ensure all manufacturers support appropriate regulation of tobacco products.

Topic: Rural Emergency Hospitals (REHs)

- Thanks to Congress’s leadership in the Consolidated Appropriations Act of 2021, CMS has implemented a new Medicare provider type, the Rural Emergency Hospital, to address the growing concern over closures of rural hospitals.
- Applications are available now for hospitals in rural areas that would like to change to this new provider type.
- The REH designation provides an opportunity for Critical Access Hospitals and certain rural hospitals that generally do not provide acute care inpatient services to avert potential closure.
- By converting to an REH, eligible rural facilities are able to provide emergency services, observation care, and additional medical and health outpatient services.
- In January 2023, CMS issued guidance regarding the REH enrollment and conversion process for eligible facilities. Some hospitals have already converted to this new provider type in 2023.

UC - Contracts for Border Services/Facilities

TALKING POINTS:

- When it comes to contracts for border services and facilities, ORR operates under the same child welfare principals that guide its core mission. Safety and well-being are at the forefront of every decision we make at HHS.
- In FY 2021, ORR faced a dramatic increase in referrals of Unaccompanied Children. Due to the need to urgently increase ORR's capacity to protect the tens of thousands of children in its care in the face of exceptional circumstances, HHS employed contracting authorities that allow federal agencies to limit competition in certain urgent circumstances.
- This was designed to avoid unacceptable delays in fulfilling ORR's need to expand its bed capacity, including by standing up emergency intake sites (EIS), to protect the safety and well-being of the children in its care.
- Through improvements in case management services across the network, increased staffing, and success of COVID-19 mitigation measures, by spring 2022, ORR was able to open back up standard network capacity, which made reliance on EIS less necessary.

QUESTIONS:

Q: HHS has awarded Family Endeavors, Inc. more than \$1 billion to provide certain facilities and services for the UC program. These contracts were not competitively awarded, and they went to a company that months earlier had hired an individual who served on President Biden's transition team. Do you think it's acceptable to award taxpayer dollars based on political support like this?

- The contracts issued to Family Endeavors were awarded under contracting authorities that allow federal agencies to limit competition in certain circumstances.
- The authorities HHS used included awarding contracts based on unusual and compelling urgency and the identification of only one responsible source—in order to avoid unacceptable delays in fulfilling ORR's need to expand its bed capacity in the face of urgent circumstances.
- I understand that the OIG is currently conducting an audit of an HHS contract award to Family Endeavors. HHS recognizes and respects the OIG's authority to conduct independent audits, and we will continue to cooperate fully with the OIG.

UC - Ft. Bliss OIG Report

TALKING POINTS:

- In 2021, ORR received an unprecedented number of UC referrals during the middle of the pandemic, straining its bed capacity and also its ability quickly recruit and staff programs across the country. As ORR worked quickly to respond to this unprecedented emergency, with limited resources, it prioritized the safety and wellbeing of children at every step. Despite challenges, and lessons learned, Fort Bliss now is a model for child centered care and case management.
- ORR continues to build capacity that enhances our ability to manage emergency response efforts by expanding bed capacity, minimizing the amount of time children stay in congregate care settings, and safely placing children with vetted sponsors. Additionally, ACF has worked to increase staff training, supports and whistleblower protections to continue to provide the safest environment possible for children.
- ACF and ORR took seriously the findings of the OIG report and had already started implementing its recommendations even before it was published. Today, the reality at ICFs like Fort Bliss and Pecos is vastly different from the snapshot that the OIG report captured during the surge – bed capacity is at a record high, and time in care for children has decreased dramatically.

Program Information

BACKGROUND:

- Any allegations of mistreatment or misconduct by contractors, federal staff, or volunteers are treated immediately with the utmost seriousness and require care providers to report and document all significant incidents in accordance with mandatory reporting laws, state licensing requirements, federal laws and regulations, and ORR policies and procedures.
- Since June 4, 2022, there are no longer any active EIS sites. Both previous EIS sites at Pecos and Fort Bliss have transitioned to Influx Care Facilities (ICF).
- The ORR EISs provided needed capacity to accept children referred by Customs and Border Protection (CBP) into ORR care where they can be safely processed, cared for, and either placed with a vetted sponsor or transferred to an appropriate ORR shelter for longer-term care. EISs provided lifesaving services for UC consistent with best practices in emergency, disaster, and or humanitarian response.
- As ICFs, Fort Bliss and Pecos help ensure that ORR can continue to promptly accept UC referrals from DHS even when ORR's standard facilities for UC are at capacity. ICFs offer the full suite of services that are available in ORR's standard network of care. ORR is committed to ensuring ICFs meet or exceed standards equivalent to state licensed facilities.
- While in ORR care, children have access to healthcare, legal services, translation services, and mental and behavioral health counselors and are able to connect with family frequently and at least twice a week. Children also meet with a case manager at least weekly.
- Training is on-going and continuous at all ICFs. ORR has partnered with NGOs, such as licensed shelter provider Children's Village (subcontracted), to provide on-site training at the ORR ICF at Fort Bliss specific to Youth Care Workers and Case Managers.
- Through its monitoring process, ORR acts quickly to address any concerns and has proactively closed sites that didn't meet our standards. All sites swiftly report any allegations to the appropriate authorities.

UC - HHS/DOL Child Labor

TALKING POINTS:

- The New York Times article demonstrates the terrible ways that employers are exploiting the economic situation that many children and families in the United States find themselves in, including children who have previously been in ORR care.
 - The previous administration left us a number of challenges to fix, and not least among them at HHS was the rebuilding of ORR and the Unaccompanied Children's Program in the face of unprecedented referrals in the midst of a global pandemic.
- We take the issue of child labor very seriously, and there are additional steps that we can take to educate children and our providers about child labor exploitation, ensure sponsors understand the hazards of child labor, and collaborate with the Department of Labor to do everything we can to reduce the likelihood that children will end up in a situation where they are exploited.
 - Of course, we always look for ways we can do better. That's why are we auditing our program to see if there's any place where we can tighten up our processes.
- Our principal responsibility is to care for unaccompanied children while they are in our custody, and then make sure we can place the child to a safe, vetted sponsor. HHS looks forward to partnering with you to advance the shared mission of protecting children and continue to strengthen the quality and depth of services we offer.

QUESTIONS:

Q: When it comes to vetting sponsors, why did HHS pair down fingerprinting and case reviews?

- First, let me start with HHS prioritizes the safety and wellbeing of every child in our care. All decisions by HHS are done with this in mind. We thoroughly vet every sponsor before placing a child in their care.
- HHS has not changed any vetting protections that would affect the safety of children in our care. In 2021, ORR received an unprecedented number of UC referrals. ORR ***did not make policy changes*** that cut out safety measures or accelerated processes that might ***put children at risk***.
- It is particularly important to prioritize timely placement with biological parents or legal guardians. This is why we updated our process when we came into office – when it comes to placing a child with their parent (or legal guardian), **we cut through the red tape** in accordance with their parental right to be unified with their children as soon as possible. We heard from advocates and stakeholders, reviewed our process, and were able to make these improvements.
- ORR has and continues to work to keep children out of large, congregate settings without sacrificing procedures that keeps them safe.

Q: Does HHS have room for improvement?

- We continuously review our policies and procedures for ways to be more efficient and effective.
- Research shows children do much better with their families and in home settings, not government funded congregate settings.
- If a safe, vetted sponsor is available, we will not delay doing what is best for the child.

Q: How does ORR check on a child's wellbeing after they are placed with a sponsor?

- While ORR's custodial responsibilities for unaccompanied children end when the child is released from ORR care, ORR engages in a range of post-release activities and assists in supporting access to such services for children and sponsors.
- We all recognize how heartbreaking the situation is, and the challenges these children face – this calls for a whole of government response (including state government, local government, and community groups), and HHS takes our part in this continuum of care seriously.
- ORR's post-release services include assistance in connecting children and their sponsors to community-based resources suitable to their needs, and support to prevent a child from becoming a victim of trafficking.

Q: The article had recordings of you that implied you were prioritizing speed of discharges over child safety. Did the pressure of the UC surge cause HHS to sacrifice standards?

- The larger context of that quote was not captured – of course my priority and the Department's priority is to keep kids safe no matter what.
- The Department does not want children to be kept in large, congregate settings unnecessarily when a safe, vetted sponsor is available. That's both our legal and moral obligation.
 - When I made those comments, we were seeing inconsistency from week to week and wanted to improve the process while continuing to provide child-centered care for children in our custody until they were released to a thoroughly vetted sponsor.
- Last summer, there was limited space and facilities to care for children, and we needed to ensure we were being efficient – not just on one day, but every day – when it came to placing the children in our care with a safe and vetted sponsor.

Q: Recent reporting shows that there has been an increase in children being released to sponsors that are not family. Is HHS prioritizing a quick release of a child over a safer release to a family member?

- That data is not accurate. In FY 2022, 85% of children were released to their immediate or extended family. In FY 2023, 34.8% of children were released to their parents, and we continue to see an increase of unaccompanied children released to their parents. Thus far, in FY 2024, 37.3% of children have been released to their parents.

Q: Are children being sent to live with strangers?

- No. While a preexisting relationship is not required for an unaccompanied child to be released to a sponsor, ORR takes this into account when determining the suitability of the case for release and may require that the sponsor, the unaccompanied child, and the child's family, establish ongoing regular contact while the child is in ORR care prior to a release recommendations. Such releases, however, are rare.

Q: Advocates are calling for more legal services. They say that HHS is sitting on money that it could use for these services. What's your response?

- HHS has already expanded legal and post release services to historic levels and has been working to expand access to these services for all children who come through ORR care – doubling the number of children and families receiving post-release services since President Biden took office.
- We will continue to work with Congress to expand post-release services to all children by 2025 and we will continue to work with advocacy organizations to build additional legal capacity that can support our goal of providing full legal services.

Q: How, if at all, does HHS coordinate with other agencies and departments, including the Department of Labor, the Department of Justice, and others, to identify and reduce child labor exploitation, including among unaccompanied children?

- As mentioned, ORR must refer any trafficking concerns to DHS to investigate any trafficking claims.
- ORR and all its network of care providers must also refer any suspected trafficking case to the Office of Trafficking in Persons (OTIP). All cases referred to OTIP are reviewed to assess trafficking concerns and connect the minors to benefits and services.

Program Information

BACKGROUND:

In addition to increasing our efforts to better inform children, sponsors and providers about child labor exploitation, there are many ways we will continue to improve how we prevent and respond to child labor issues. They include:

- **DOL-led Task Force:** HHS will participate in a new interagency initiative with the Department of Labor, which will focus on improved information sharing related to labor investigations, enabling HHS to increase scrutiny in the sponsor vetting process when appropriate.
- **Post-Release Services:** We have been building capacity on post release services and we are on track this year to serve more than 50% of children released with such services. HHS will continue to work with Congress to ensure we have the funding to build on this expansion of post-release services with the goal of having capacity to serve all children and sponsors within the next two years.
- **Audit of Sponsor Vetting Process:** We will continue to review current policies regarding vetting requirements for potential sponsors who have previously sponsored unaccompanied children to ensure all necessary safeguards are in place without unnecessarily keeping kids in government-funded congregate care settings.
- **NCC Follow Up Call and Training Improvements:** We are working with the National Call Center (NCC) to require a new follow-up call for former unaccompanied children who contact the helpline with safety concerns.

UC - ORR/Migrant Flights

TALKING POINTS:

- This is an issue where misinformation has run rampant, and I want to set the record straight. It is our legal responsibility to provide safe, appropriate care to unaccompanied migrant children during the time they are in our custody, and that includes transportation to appropriate shelter placements and to unify with their vetted sponsors while they await immigration proceedings.
- There are no secret flights. And these flights are different and unrelated to the ones folks may have heard about on the news, such as the flights of migrant families to Martha's Vineyard. These flights to transfer UCs to their sponsors or to our network of over 200 shelter facilities in 22 states take place in accordance with the law and our responsibilities.
- Staff supervise and escort UC until they are placed in the care of another ORR facility or a vetted family member or sponsor. This has been the policy across multiple administrations since 2014. Transportation is coordinated, and clearly communicated to all appropriate parties, from a secure ORR facility to a vetted family member or sponsor or other ORR facility that is ready and awaiting the arrival of the UC. Through case management services, UC are always aware of where they are going and why.

Program Information

BACKGROUND:

ORR utilizes both commercial and charter ground and air transportation options to facilitate the transportation of unaccompanied children. Travel logistics, whether for transfer or sponsor placement or reunification purposes, are determined on a case-by-case basis with consideration of the child's best interest. Travel may be facilitated by either ORR care provider staff or ORR's transportation contractor. Both entities coordinate transportation logistics and supervise and escort the children until they are safely placed in the care of the receiving ORR facility, or a vetted family member or other sponsor. Travel may be coordinated outside normal business hours to ensure there are no unnecessary delays in the transfer or unification process. All such travel takes place in accordance with applicable law and regulations, as it is ORR's responsibility to ensure the safety of unaccompanied children in its custody. Transportation is coordinated, and clearly communicated to all appropriate parties – the child, the ORR facility, and the vetted family member or other sponsor or other ORR facility that is ready and awaiting the arrival of the child.

ORR publishes state-by-state data of unaccompanied children released to sponsors on its website. This data is also broken out by County. ACF aims to update this on a monthly basis.

UC - Reproductive Health

TALKING POINTS:

- ORR has a moral and legal obligation to safely and humanely care for all unaccompanied children referred to us. HHS works with our partners across the government to ensure that unaccompanied children are safe and provided – in accordance with the Flores Settlement Agreement and *Garza* – appropriate routine medical care, family planning services, access to reproductive health services, and emergency contraception and health care services.
- The Department's priority is to ensure that the populations we serve receive the reproductive care they need while following applicable legal requirements. ORR decision making is rooted in an ongoing assessment of the best interests of the child and established child welfare best practices.
- We remain committed to clearly explaining the care available and providing referrals or arranging appointments with healthcare providers which may include arranging and funding travel from states where laws may restrict care to states where necessary care is available.

QUESTIONS:

Q: What reproductive services are available to minors in ORR care?

While in ORR care and custody, UC have access to family planning services and reproductive health care. Services include: pregnancy testing, emergency contraception, and comprehensive information about and access to reproductive health services. ORR also ensures access to oral contraceptive pills that are prescribed by a healthcare provider for a medically indicated diagnosis. ORR ensures that pregnant UC receive non-directive pregnancy options counseling when necessary and that appropriate specialty care referrals are made as soon as UC is discovered to be pregnant for further evaluation and care.

Q: What policies does ORR follow in regard to abortion?

The UC program and its policies are aligned with the Flores Settlement Agreement, the Homeland Security Act, the Trafficking Victims Protection Reauthorization Act, and the ORR Policy Guide. ORR care providers are also typically state-licensed and therefore must abide by the healthcare requirements applicable in each relevant state.

Q: How does ORR protect the first amendment rights of federal staff and care provider staff who have personal/faith-based objection to abortion?

- Nothing in existing *Garza* policy prohibits ORR from providing accommodations to care providers who maintain a sincerely held religious objection to abortion; rather ORR does provide such accommodations.
- If a faith-based care provider has a religious objection to abortion, and a UC in the care of such a provider is discovered to be pregnant, ORR's field staff will personally deliver any legally required notice to the UC orally and in writing, along with other pregnancy-related information required by ORR policy.

- Faith-based providers are critical partners for our mission. ORR operates 102 different faith-based providers in at least 18 states.

Q: What if UC in care does not want an abortion? What care is provided to them?

- ORR is required to provide pregnant UC non-directive options counseling. UC are notified that neither the federal government, nor care providers, may obstruct or interfere with UC accessing counseling about all the options they have regarding their pregnancy.
- UC in ORR care can decide whether to continue their pregnancy or terminate the pregnancy.

Q: How many pregnant UCs have given birth (and kept) their babies? How many UCs have requested abortion since the passing of the Dobbs decision? How many abortions does ORR pay for each year?

ORR does not disclose this information to protect children's medical and health privacy, especially given that this is a very small number.

Q: What about the Hyde Amendment? How are federal funds being used to provide abortions for UC?

Nothing in the ORR Garza policy supersedes applicable Federal appropriations restrictions such as those outlined in the Hyde Amendment.

Q: Does the government pay for transportation of UC across state lines to access abortion services? Is this true for Hyde Amendment and non-Hyde Amendment abortions?

ORR regularly facilitates access to medical services for UC, including transporting UC across state lines, when necessary. The care provider is responsible for transporting the UC to medical appointments, including access to reproductive health care across state lines. Where a religious exemption is in place, ORR staff may assist with the transportation of the UC to seek abortion services.

Q: Does the government pay for lodging, translation, and other ancillary services, in the course of facilitating access to abortion services? Is this true for Hyde Amendment and non-Hyde Amendment abortions?

Yes, the government may fund lodging, translation, and other ancillary services in the course of facilitating access to abortion, regardless of whether the pregnancy meets the Hyde Amendment specifications or not. Care providers and child advocates may receive donations to help pay for some of these expenses on an as-needed basis.

Q: Does ORR prohibit access to abortion past a certain gestation (“late-term pregnancy”)?

ORR federal staff and care provider staff will assist in facilitating an abortion request by a UC, based on the available in consultation with DHUC, in compliance with *Garza* requirements and the Hyde Amendment. The time limit for an abortion procedure prescribed to the UC is in the purview of the medical provider and the UC and is not the purview of ORR.

UC - Sponsor Vetting/Post-Release Services

TALKING POINTS:

- Safety and well-being are at the forefront of every decision we make at HHS. Child welfare best practices are clear that the best place for a child is in a community with family and not in large congregate care settings. Once we identify a safe, vetted sponsor, who has undergone a robust screening process, we have a responsibility to place the child as quickly as possible.
- We also understand the importance of providing children and sponsors with the tools and resources necessary to help a child succeed post-release and develop permanent connections for support and resilience as a child transition into a new community.
- HHS has already expanded legal and post release services to historic levels and has been working to expand access to these services for all children who come through ORR care – doubling the number of children and families receiving post-release services since President Biden took office.
- HHS will continue to work with Congress to ensure we have the funding to build on this expansion of post-release services with the goal of serving all children within the next two years. It will also continue to evaluate pathways to strengthen

QUESTIONS:

Q: When it comes to vetting sponsors, why did HHS pair down fingerprinting and case reviews?

- First, let me start with HHS prioritizes the safety and wellbeing of every child in our care. All decisions by HHS are done with this in mind. We thoroughly vet every sponsor before placing a child in their care.
- HHS has not changed any vetting protections that would affect the safety of children in our care. In 2021, ORR received an unprecedented number of UC referrals. ORR ***did not make policy changes*** that cut out safety measures or accelerated processes that might ***put children at risk***.
- It is particularly important to prioritize timely placement with biological parents or legal guardians. This is why we updated our process when we came into office – when it comes to placing a child with their parent (or legal guardian), **we cut through the red tape** in accordance with their parental right to be unified with their children as soon as possible. We heard from advocates and stakeholders, reviewed our process, and were able to make these improvements.
- ORR has and continues to work to keep children out of large, congregate settings without sacrificing procedures that keeps them safe.

Q: How does ORR check on a child's wellbeing after they are placed with a sponsor?

- While ORR's custodial responsibilities for unaccompanied children end when the child is released from ORR care, ORR engages in a range of post-release activities and assists in supporting access to such services for children and sponsors.

- We all recognize how heartbreaking the situation is, and the challenges these children face – this calls for a whole of government response (including state government, local government, and community groups), and HHS takes our part in this continuum of care seriously.
- ORR's post-release services include assistance in connecting children and their sponsors to community-based resources suitable to their needs, and support to prevent a child from becoming a victim of trafficking.

Q: Recent reporting shows that there has been an increase in children being released to sponsors that are not family. Is HHS prioritizing a quick release of a child over a safer release to a family member?

- That data is not accurate. In FY 2022, 85% of children were released to their immediate or extended family. In FY 2022, 34.8% of children were released to their parents, and we continue to see an increase of unaccompanied children released to their parents. Thus far, in FY 2023, 37.3% of children have been released to their parents.

Q: Are children being sent to live with strangers?

- No. While a preexisting relationship is not required for an unaccompanied child to be released to a sponsor, ORR takes this into account when determining the suitability of the case for release and may require that the sponsor, the unaccompanied child, and the child's family, establish ongoing regular contact while the child is in ORR care prior to a release recommendations. Such releases, however, are rare.

Q: What exactly is the process for vetting sponsors?

- The process includes a proactive search by the care provider for a potential sponsor; a written sponsor application; interviews; required documentation establishing sponsor identity, address, relationship to the child, and other supporting documentation; background checks; and home studies as required by law and in ORR's discretion consistent with its policies.
- ORR thoroughly screens sponsors through tools that may include public records checks, sex offender registry checks, and fingerprinting.

Q: Why would numerous unaccompanied children be released to the same address?

There might be various reasons why several children are released to sponsors at the same address including a large apartment complex or other address with multiple units. ORR has systems in place that alert users when sponsors are concurrently sponsoring other children or have sponsored other children in the past. If ORR records show that multiple children are being released to the same address, ORR might conduct additional checks, such as requiring home studies before releasing other UC to those locations.

UC - Transgender Care

TALKING POINTS:

- ORR has a moral and legal obligation to safely and humanely care for all unaccompanied children referred to us. That means that *all* children and youth in ORR care are entitled to human rights protections and freedom from discrimination and abuse, no matter their gender or sexuality.
- Care providers must ensure that LGBTQI children are fairly treated and served and are not discriminated against during their time in ORR care. That means in part that they must maintain privacy and confidentiality of information concerning sexual orientation and gender identity. They need to use correct names and pronouns in accordance with the youth's gender identity. They must house LGBTQI youth according to an assessment of the youth's gender identity and housing preference, health and safety needs, and State and local licensing standards.
- While we have a guide for provider obligations with respect to LGBTQI children and youth in ORR care, ORR does not currently have any other policy on access to gender-affirming care. Faith-based providers are critical partners for our mission. ORR does not have specific policy concerning faith-based grantees and care for transgender UCs. This is a new policy area for ORR, and we continue to study the issue for policy development.

QUESTIONS:

Q: Does ORR provide gender-altering healthcare to UC at their request? Are there examples of this happening?

- UC Policy Guide 3.5 outlines care provider obligations with respect to LGBTQI children and youth in ORR care. The ORR UC Program does not currently have any other policy on access to gender-affirming care.

Q: Does ORR allow for male children to reside in female residential areas and utilize female restrooms just because they say so?

- To provide the least restrictive placement suitable for each child and ensure the safety and wellbeing of children in care, ORR considers all available information when making placement decisions, including the child's identity documents, physical anatomy, and self-identification of their gender and safety needs when determining the child's housing and service allocation.
- Care providers must offer an individualized assessment to determine whether additional or alternate restroom accommodations should be provided. UC are always supervised and ORR's priority is the safety of all children in its care.

Q: What is a woman?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- Support youth and families; HHS commitment to advance safety and support for LGBTI+ youth. Access to gender affirming care, when medically necessary can be lifesaving.
 - Ensuring such access is the law.

Q: How many genders are there?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- At HHS, we are committed to advancing health equity for people of all genders. Health equity is defined by HHS Healthy People 2030 as the “attainment of the highest quality of health for all people.” We work toward that goal every day.

Q: Does HHS support irreversible genital surgeries on children?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

Q: What other requirements are providers supposed to adhere to in regard to LGBTQI children?

- They must maintain privacy and confidentiality of information concerning sexual orientation and gender identity.
- They need to use correct names and pronouns in accordance with the youth’s gender identity. They must house LGBTQI youth according to an assessment of the youth’s gender identity and housing preference, health and safety needs, and State and local licensing standards.
- They must offer an individualized assessment to determine whether additional or alternate restroom accommodations should be provided.
- They must allow LGBTQI youth to dress and express themselves according to their gender identity.
- They must allow LGBTQI youth to choose the gender of staff to conduct a pat-down search if one is necessary.

UC - Violent/Criminal Former UCs

TALKING POINTS:

- This administration takes all cases of violent crime seriously, no matter the immigration status of the alleged criminal, or whether the individual was formerly in the custody of ORR care. While we remain committed to working with Congress to comprehensively fix the problems of a long-broken immigration system, ORR is not an immigration enforcement entity. It is ORR's legal responsibility to provide a safe environment for all children in its care.
- Since 2019, ORR has made significant improvements to assess and address its network capacity to better serve the needs of children with mental health and behavioral issues, including seeking and coordinating increased mental health and treatment services for shelter cases needing specialized placement.
- While ORR's custodial responsibilities for unaccompanied children end when the child is released from ORR care, ORR engages in a range of post-release activities and assists in supporting access to such services for children and sponsors. We have been building capacity to increase post release services and we are on track this year to serve more than 50% of children released from our care.
 - HHS will continue to work with Congress to ensure we have the funding to build on this expansion of post-release services with the goal of serving all children within the next two years.

QUESTIONS:

Q: The Biden Administration's open-border policies created vulnerabilities that criminals and gang members exploit. What is the Department doing

Refer to CBP and DHS for specific questions on immigration policy. Again, ORR is not an immigration enforcement or law enforcement entity.

Q: What is HHS doing to verify whether UCs referred to their care are members of MS-13 or other violent gangs?

- HHS is required to ensure the safety and care of all unaccompanied children in ORR custody. Pursuant to the Trafficking Victims Protection Reauthorization Act, ORR is required to provide safe and secure placement for children. In addition, the *Flores* Settlement Agreement also outlines factors HHS must consider when ORR is making placement determinations, such as screenings for self-harm, harm to others, and flight risk. These requirements are reflected in ORR's UC Program Policy Guide (Section 1.2.4).
- HHS does not have the authority to conduct background checks on unaccompanied children. Prior to the Department of Homeland Security referring children to ORR custody, DHS fingerprints all children over the age of 14, and if there is criminal history

based on those biometrics, these are reported to ORR as obligated under the 2021 HHS and DHS Memorandum of Agreement. This MOA creates an affirmative obligation for DHS to provide the criminal history, gang affiliation, court docs, etc. for an unaccompanied child upon their referral to HHS. If made aware of additional DHS documents or court records, ORR will also seek these records.

Q: There have been reports that there has been a rise in missing unaccompanied children across the country. Is ORR tracking these children after release?

- Though ORR does not have custody of children after they are discharged, ORR provides safety and wellbeing calls to all children, and post-release services and legal representation to many children. ORR cannot compel former unaccompanied children or sponsors to respond to inquiries or participate in these services. There are many reasons why discharged unaccompanied children, who often live in mixed-immigration-status families, may not want to be contacted by the U.S. government.

Program Information

BACKGROUND:

ORR policies for placing children and youth in its custody into care provider facilities are based on legal requirements as well as child welfare best practices in order to provide a safe environment and place the child in the least restrictive setting appropriate for the child's needs.

ORR has hired a Field Supervisor for Special Populations to oversee care and treatment services for children in secure, staff secure, and residential treatment center placements. ORR's Mental and Behavioral Services Team is working to integrate clinicians as part of the care providers' medical teams to assess the health needs of every child in ORR care.

Vulnerable Children + Youth

(Dollars in Millions)

Discretionary Funding	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Runaway & Homeless Youth	146	159	+13
Child Abuse Programs	214	257	+43
Child Welfare Programs	339	431	+92
Adoption Incentives	75	75	-
Family Violence Prevention Services	261	519	+259
Total Vulnerable Populations Program Level	1,226	1,683	+457

TALKING POINTS:

- It is the Department’s responsibility to protect those most vulnerable among us – and that means making robust investments in care settings and supports for children in the foster care system, investments in children and youth in at-risk situations, and investments in family violence and child abuse prevention programs.
- This Administration is delivering on that mission with its FY24 budget, which increases funding for vulnerable populations across the board. To start, this budget nearly doubles funding for Family Violence Prevention Services Programs from last year’s enacted levels.
- HHS is also committed to reducing child abuse and providing families with the support they need to remain safely together to avoid the trauma that results when children are placed in out-of-home-care – that’s why we asked for a \$135 million increase to continue to support child welfare.
- These issues have historically had bipartisan consensus. The Department looks forward to continuing to partner with Congress to advance a child-centered and family-centered social service infrastructure.

QUESTIONS:

Q: We just marked 5 years since the bipartisan passage of the Family First Act – can you speak to how implementation is going across the country?

The Family First Prevention Services Act (FFPSA) and its title IV-E prevention services program provides a watershed opportunity to create more equitable outcomes for children, youth, and families before they face the tumult and devastating consequences of maltreatment and separation.

ACF estimates that 6,200 children were served by title IV-E prevention services programs in FY 2022, and, as more and more prevention programs are implemented, 672,500 children will be served annually by FY 2033

We have seen great progress around the country among jurisdictions who have developed prevention plans under Family First to expand the in-home parenting skills programs, mental health programs, and substance use prevention and treatment programs in their communities.

Q: Family members are often an important part of our child welfare system, keeping kids safe, and keeping families together. What is the Administration doing to ensure that family members caring for children have the supports they need?

When parents are unable to safely care for their own children, it is often grandparents, other family members, or kin who step forward to provide a loving home for those children, either temporarily or permanently. Research is clear that children in kinship care often experience less trauma and have better outcomes across a range of behavioral and developmental well-being measures.

While kinship caregivers provide essential care to children, they often do not receive adequate support.

The Biden-Harris Administration is committed to strengthening support for grandparents and other kin caring for children by working with states to ensure equitable access to licensure for relative foster care providers and by expanding services, resources and supports for kinship caregivers and the children in their care.

The President's FY 2024 budget includes proposals to encourage placing children with relatives or kin when they cannot remain safely at home with parents.

The President's FY 2024 budget also proposes to increase support for kinship navigator programs.

Program Information

Runaway and Homeless Youth

One in thirty adolescents between the ages of 13-17, and one in ten adults between the ages of 18-25 experience homelessness over the course of the year. This is approximately 4.2 million youth and young adults. The budget includes \$159 million for RHY programs, which is \$13 million above FY 2023 enacted. The budget will serve 688 programs across the country to provide comprehensive services to an estimated 39,876 homeless youth who are at heightened risk for exploitation, victimization, and other long-lasting, negative outcomes.

Child Welfare

ACF will provide \$50 million in new competitive grants to address racial inequities in child welfare, reduce overrepresentation of racial/ethnic minority children and families, and reorient systems toward a prevention-first model.

FVPS Program

The Family Violence Prevention Services program is the primary federal funding stream supporting emergency shelter and related services to survivors of domestic violence and their children. In 2021, grantees served over one million clients through 1,600 organizations. This budget requests \$519 million, double the FY 2023 enacted amount. It includes \$27 million for the Domestic Violence Hotline, which has experienced a historic rise in contact volume since FY 2021. The request also provides \$225 million for direct cash assistance to survivors of domestic violence. Domestic violence is a leading cause of homelessness and direct cash assistance allows survivors to have stable housing.

World Health Organization (WHO)

TALKING POINTS:

- We know that the challenges we face won't be solved by one leader or one country alone, but by the world coming together and fighting for what's right.
- The WHO is an essential organization; they are the only international organization with the mandate and convening power to bring together Ministries of Health and health experts across 194 countries.
- I strongly support the ongoing efforts to strengthen the WHO and make it more agile, transparent, efficient, and accountable.

QUESTIONS:

Q: Do you commit to voting against any reform in the Pandemic Accord or to the IHR that would violate the United States' sovereignty?

- The United States will not support any measure at the World Health Organization, including in these negotiations, that in any way undermines our sovereignty or security.
- Any accord resulting from these negotiations would be designed to increase the transparency and effectiveness of cooperation among nations during global pandemics and would in no way empower the WHO or any other international body to impose, direct, or oversee national actions.
- It will not compromise the ability of American citizens to make their own health care decisions.

Q: What steps will you take to ensure WHO adequately responds to allegations of widespread sexual abuse and exploitation?

- There must be zero tolerance for sexual exploitation and abuse at the WHO.
- HHS, State, and USAID have been working closely with the WHO as they respond to sexual exploitation and abuse allegations and work to build stronger systems to prevent and address this in the future.
- The WHO has made improvements and laid out a Management Response Plan with next steps to continue progress, but our pressure on these issues must continue to be a top priority.

Q: Do you support obligating the United States via international agreement to provide reproductive health services, including abortion, as essential health care during a pandemic?

I will comply with all legislative restrictions on foreign assistance related to abortion, including restrictions against advocating for or against abortion in multilateral fora.

Q: It was recently reported that WHO was abandoning its investigation into the origins of the coronavirus. Do you think now is the time for international organizations like WHO to give in to China's obstruction and give up on this investigation?

- No. For more than two years, China has blocked international investigators and members of the global public health community from accessing information related to COVID-19 origins. This is unacceptable – and we must not let this prevent us from getting answers.
- If we're going to get to the bottom of this question, we need critical information about the origins of this pandemic that exists in the People's Republic of China.
- International investigators and members of the global public health community should have access to it.

Workforce – Head Start / Child Care

TALKING POINTS:

- Head Start cannot fulfill its mission to serve children and families from vulnerable communities without a robust, well supported workforce.
- Head Start preschool teachers earn drastically less than kindergarten teachers with the same credentials, which limits a program's ability to recruit and retain staff.
- The budget would provide a much-needed investment to stabilize the workforce, including \$440 million for a cost-of-living adjustment for Head Start wages to keep pace with inflation. The budget also directs \$575 million to improve compensation for Head Start workers.
- We continue to explore how federal policy can better support the Head Start and child care workforce, as well as how to leverage opportunities available from partners at the local, state, and federal levels.

Background

The budget requests \$13.1 billion, an increase of \$1.1 billion above FY 2023 enacted, to provide comprehensive early learning and development services to infants, toddlers, and preschool-aged children from economically disadvantaged families. This funding includes \$440 million for a cost-of-living adjustment for Head Start wages to keep pace with inflation. The budget also directs \$575 million to improve compensation for Head Start workers. This investment reflects the Administration's priority of building and retaining a strong early childhood education workforce. The Administration continues to invest \$100 million in Early Head Start-Child Care Partnerships. The partnership's funding provides comprehensive and continuous Early Head Start and child care services to low-income families with infants and toddlers. These investments will serve an estimated 813,573 children and families through nearly 1,600 local agencies in states, territories, and tribes across the United States.

Workforce - Health Care

TALKING POINTS:

- The need for a strong and robust healthcare workforce could not have been more apparent than during the height of the COVID-19 pandemic.
- We must continue to invest robustly in training, ongoing education, and mental well-being of our health care workforce.
- HHS has invested **hundreds of millions of dollars** in the health care workforce over the past year.
 - Over the next 5 years, we will create **1,000 new Graduate Medical Education (GME) slots**. The first 200 GME slots were created at the beginning of 2023. Specifically focused on primary and mental health care providers.
 - We've invested **\$103 million** to provide resources to support health care workers and **prevent burnout**.
 - The National Health Service Corps is at its largest field strength, over **20,000 members**, serving at more than **9,000 community health care centers** seeing more than **21 million patients**.
 - Awarded **\$225 million** to train **13,000 community health workers** to strengthen the public health care workforce to prepare for future public health threats.
- The President's Budget for FY 2024 seeks to extend and expand funding for these programs to ensure that recent gains and funding capacity on these programs is not lost.

QUESTIONS:

Q: How does the Budget increase and strengthen the health workforce in response to health workforce shortages?

- The FY 24 Budget has several initiatives that will grow, diversify, and promote the well-being of the health workforce. The Budget proposes to:
 - Extend and increase mandatory funding for National Health Service Corps and Teaching Health Center Graduate Medical Education for 3 years through FY 2026.
 - Provide scholarships and loan repayment to clinicians in return for practicing in underserved areas and support over 20,000 providers (National Health Service Corps, \$965.6 million, an increase of \$547.7 million).
 - Funds over 1,400 primary care physicians and dental residents in community-based training (Teaching Health Center Graduate Medical Education, \$157 million, an increase of \$37.7 million).
 - Train Certified Nurse Midwives and to expand and modernize nursing education programs by increasing nurse faculty (\$349.9 Million, an increase of \$49.5 million, for the nursing workforce).
 - Train 18,000 more mental health and SUD providers (\$387.4 million, an increase of \$190.3 million, for Behavioral Health Workforce Development Programs).
 - Seed new approaches with a new Health Care Innovation Workforce program to grow the health care workforce and address shortages (\$27.5 million).

Internal Use Only – U.S. Department of Health and Human Services

- Expand the diversity of the health professions workforce (\$110.2 million, an increase of \$10.7 million).
- Support the behavioral health, and well-being of health care providers (\$25 million).

Q: If the NHSC received all of the funding requested in the President’s Budget, will it eliminate workforce shortages? What would you need to close out the primary care shortages?

- The Budget would sustain and expand the record number of providers currently providing care or getting trained to serve in underserved and rural communities.
- Eliminating larger provider shortages would require a broader approach to build the pipeline, expand training capacity, and provide incentives for providers to go into communities with shortages, as well as increasing the number of other health care providers that comprise the care team, such as nurses, physician assistants, medical assistants, lab technicians and others.

Q: What are the consequences of not extending mandatory funding for the Teaching Health Center Graduate Medical Education Program?

- If funding is not received, hundreds of medical residents currently being trained in community-based settings could face interruption or termination of their residency programs.
- Without renewed funding, Teaching Health Centers may reduce the number of available training slots and some programs may close entirely.

Workforce - Mental Health

TALKING POINTS:

- HHS is committed to strengthening and expanding the workforce to respond to the mental health and substance use disorder crisis.
- We've been hard at work – working with Congress we've created new Graduate Medical Education slots, invested in resources to prevent burnout, funded training of community health workers, and more.
- But much more can and should be done. That is why the budget invests in the behavioral health workforce by supporting an estimated 27,000 total mental health and substance use disorder trainees and providers.
- Specifically, the budget proposes \$387 million for Behavioral Health Training Programs, an increase of +\$190 million, to grow the number of behavioral health professionals through training approximately 18,000 behavioral health providers; such as psychiatrists, psychologists, clinical social workers, marriage and family therapists, counselors, and peer support specialists.

QUESTIONS:

Q: What has HHS done to expand the mental health workforce?

- Working with Congress, HHS has invested **hundreds of millions of dollars** in the health care workforce over the past year.
 - Over the next 5 years, we will create **1,000 new Graduate Medical Education (GME) slots**. The first 200 GME slots were created at the beginning of 2023. Specifically focused on primary and mental health care providers. An additional 200 GME slots were added by CAA 2023, with 100 dedicated to psychiatry or psychiatry subspecialty residency positions.
 - We've invested **\$103 million** to provide resources to support health care workers and **prevent burnout**.
 - The National Health Service Corps is at its largest field strength, over **20,000 members**, serving at more than **9,000 community health care centers** seeing more than **21 million patients**.
 - Awarded **\$225 million** to train **13,000 community health workers** to strengthen the public health care workforce to prepare for future public health threats.
 - Next year, Medicare will finally **provide payment to care provided by therapists and Licensed Professional Counselors**.

Q: What else do you think needs to be done to expand the workforce?

- The FY 24 Budget has several initiatives that will grow, diversify, and strengthen the mental health workforce. The Budget proposes to:
 - Train 18,000 more mental health and SUD providers (\$387.4 million, an increase of \$190.3 million, for Behavioral Health Workforce Development Programs).

Internal Use Only – U.S. Department of Health and Human Services

- Provide scholarships and loan repayment to clinicians in return for practicing in underserved areas and support over 20,000 providers (National Health Service Corps, \$965.6 million, an increase of \$547.7 million). The NHSC supports primary care medical, dental, and behavioral health providers through scholarships and loan repayment programs.
- Allocate \$37 million for the Minority Fellowship Program (MFP) to almost double the number of fellows in FY 2024. The budget also proposes to add a service requirement to ensure participants are supporting communities in need, as well as to add addiction medicine, and sexual and gender minority populations as participants in the program. .
- Allow Medicare to designate additional professionals such as clinical social workers, peer support workers, and certified addiction counselors to furnish behavioral health services within their applicable state licensure or scope of practice – the proposal builds CAA 2023’s coverage for behavioral health services furnished by marriage and family therapists and mental health counselors.

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340B Program

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		President's Budget	+/- FY 2023 Enacted
340B Drug Pricing Program/Office of Pharmacy Affairs	12,238	17,238	+5,000

TALKING POINTS:

- The 340B Program is a critical drug discount program for safety net providers that serves **every congressional district** in the country.
 - Eligible entities include community health centers, Ryan White HIV/AIDS clinics, rural hospitals, and children's hospitals.
- I know that **program integrity** is critical and that is why the President's budget includes proposals to strengthen compliance, transparency and integrity of the program.
 - Right now, HHS does not have the authority to require reporting by covered entities on how they spend their savings. This budget requests new regulatory authority to require covered entities to annually report to HHS how the savings achieved through the Program benefits the communities they serve.
 - The Budget also proposes explicit regulatory authority to strengthen compliance and transparency related to the use of contract pharmacies.
- The Biden-Harris Administration is committed to **lowering the cost of drugs** and increasing access to affordable care. The 340B program is critical to this work and I look forward to working with Congress on these proposals to strengthen the program.

Questions:

Q: What is in the FY 2024 Budget for the 340B program? Why are you asking for more funding if the hospitals are exploiting the program?

- The FY 2024 Budget Request for the 340B Program is \$17.2 million, an increase of \$5 million over FY 2023, to strengthen the program's operations.
- The FY 2024 Budget includes a proposal to enhance 340B Program integrity by requiring covered entities to annually report to HHS on how the savings achieved through the Program benefits the communities they serve and provide HHS regulatory authority to implement this requirement.
- The Budget also proposes explicit regulatory authority to strengthen compliance and transparency related to the use of contract pharmacies.
- We look forward to working with Congress on these proposals to strengthen the 340B Program.

988 Implementation

TALKING POINTS:

- 988 is more than a number, it's a message: we're there for you. The transition to 988 is just the beginning. We are working towards comprehensive, responsive crisis care services nationwide to save lives.
- Investments in the 988 Lifeline through FY23 appropriations and the Bipartisan Safer Communities Act expanded lifesaving behavioral health services across the country.
- The FY24 budget requests an increase of over \$334 million to scale and strengthen the 988 crisis care enterprise for the 9 million contacts anticipated in FY2024.

QUESTIONS:

Q: How many contacts did the Lifeline answer last year? How quickly?

- From July 2022 to January 2023, the 988 Lifeline answered 2,248,545 million contacts.
- Thanks to historic investments made by Congress, calls answered increased by 57%, chats answered increased by 264%, and texts answered increased by 1608% between January 2022 and January 2023.
- The average speed to answer across all contacts decreased from 181 seconds to 40 seconds.

Q: Does the 988 Lifeline take calls in Spanish?

- Yes, in 2022, the 988 Lifeline increased the number of call centers taking Spanish calls -- this includes, most recently, Beacon in New Hampshire and Linea Pas in Puerto Rico, which were both added in November.
- SAMHSA is working to add Spanish chat and text services by October of this year and is focused on supporting the Spanish crisis center workforce with trainings and webinars in Spanish.

Q: I heard that there was a Lifeline outage in December 2022 as a result of a malicious attack. What steps is SAMHSA taking to ensure that the Lifeline is secure?

Our highest priorities are to develop additional redundancies in the event of any future outages, minimize the likelihood of these events, continue to protect personal information, and to be sure there are clear communications protocols among partners and the public to quickly resolve problems if they arise.

Q: What is the response rate right now for text, chat and calls?

- The total overall contacts has been above 400k each month and continues to trend up. Accordingly, we are projecting roughly 6 million contacts for FY2023 and the need to support 9 million contacts in FY2024.

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- Since July 2022, we have maintained above a 95% response rate for chat and text.
- There was increase in the call response rate from Aug (i.e., 84%) to Jan (i.e., 88%). This is also notable as the contacts increase and we work to expand access and strengthen the network.

Q: Was any personal information obtained, as a result of this attack?

- Based on all available evidence that we have reviewed at this point, it is unlikely that any data were breached or exfiltrate

Abortion Riders

TALKING POINTS:

- I understand people have deeply held beliefs on this issue and I respect that.
- Reproductive health decisions should be between a patient and doctor.
- HHS will continue to enforce the law.

Questions:

Q: The budget excludes the Hyde amendment. Are you going to ignore the law?

- As you know, this is a provision included in funding bills passed by Congress, so it will be up to Congress on whether that changes.

Q: Do you support partial-birth abortion?

- I support access to reproductive care, including safe and legal abortion care.
- Reproductive health decisions should be between a patient and doctor.
- HHS will continue to follow the law.

Q: The Budget still leaves in place the Weldon Amendment and other abortion riders for other federal programs like IHS or FEHBP. Do you support this?

- The President has made clear that removing barriers to accessing reproductive care is a priority. The budget takes important steps to remove such barriers.
- Ultimately, removing the appropriations policy riders that restrict access to abortion is up to Congress and HHS will continue to enforce/follow the law.

ACA: Short Term Limited Duration Insurance (STLDI) Plans

TALKING POINTS:

- Making sure that all Americans have access to quality, affordable health care is one of the Biden-Harris Administration's top priorities.
- Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it.
- To make sure consumers are protected and understand the health insurance they are buying, the administration has stated its intention to revise the short-term limited duration insurance plan regulation.

QUESTIONS:

Q: Many Americans rely on Short-Term, Limited Duration Insurance plans because they are cheaper and don't come with all the unnecessary coverage mandated by the Affordable Care Act. Choice is so important in driving down the cost of insurance, so why are you committed to getting rid of this choice for consumers?

- Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. STLDI plans are exempt from critical Federal requirements for health insurance such as those contained in the Affordable Care Act. I am focused on expanding access to quality health insurance for all Americans, including ensuring consumers with pre-existing conditions are fully protected.

Q: Junk plans continue to trick consumers into buying their shoddy products. When will the Biden Administration take action to limit the availability of Short-Term, Limited Duration insurance plans?

- Thank you for your work on this issue. You're right. Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. To that end, this administration has stated our intention to propose amendments to the definition of 'short-term, limited-duration insurance' under the Public Health Service Act. At HHS, we are focused on making sure that all Americans have access to quality, affordable health care, and I would be happy to keep working with you on this issue.

ACA - Standardized Plans

TALKING POINTS:

- The Biden-Harris Administration has made it a priority to build on the success of the Affordable Care Act (ACA) by continuing to invest in and strengthen the law.
- Thanks to the American Rescue Plan (ARP) and Inflation Reduction Act (IRA), more people this year continued to qualify for help purchasing quality health coverage with expanded financial assistance, and a record-breaking more than 16.3 million people signed up for high-quality, affordable health insurance through the ACA Marketplaces during the 2023 Marketplace Open Enrollment Period.
- In accordance with President Biden's Executive Order on Promoting Competition in the American Economy, and based on new measures finalized in regulation, we have taken additional steps to further simplify the consumer shopping experience beginning in 2023 by requiring issuers offering Qualified Health Plans on HealthCare.gov to also offer standardized plan options.

QUESTIONS:

Q: There is no one-size-fits-all plan design that meets every enrollee's unique health needs. Won't standardized plans unnecessarily restrict consumers choices?

- Issuers are allowed to offer non-standardized plans.
- Standardized plans do not standardize covered benefits.
- Standardized plans help consumers better express their preferences with their plan selections.
- With standardized maximum out-of-pocket limitations, deductibles, and cost-sharing features, consumers are now able to more easily and meaningfully directly compare plans attributes they most care about, such as premiums, provider networks, prescription drug coverage, and quality ratings when choosing a plan, rather than trying to weigh the impacts of small variations in copays or co-insurance requirements that are unlikely to be known by the consumer.
- These standardized plan options also expand the availability of coverage for services before consumers meet their deductibles (including for prescription drugs at the generic and preferred brand tiers at most metal levels), which makes it easier to access important services.

Q: Why is HHS proposing to limit consumer choice in the 2024 Payment Notice? Why do you want to eliminate plan options?

- In the 2024 Payment Notice proposed rule, HHS proposed to limit the number of non-standard plans that marketplace issuers can offer up to two non-standardized plan options per product network type and metal level (excluding catastrophic plans), in any service area for 2024 and later years.

- The average number of plans available to consumers on the Marketplace has increased from 25.9 in 2019 to 113.6 in 2023 – a more than fourfold increase in just four years.
- A large body of research indicates that having this excessive rate of plan proliferation increases the risk of plan choice overload, which limits consumers' ability to make a meaningful selection when comparing plan offerings and increases the risk of suboptimal plan selection – and thus unexpected financial harm for consumers who can least afford it.
- The marketplace is made up of very active consumers. For example, each year, approximately 75% of returning consumers come in to shop and actively select their plans.
- In the 2024 Payment Notice proposed rule, we sought comment on this and other issues related to simplifying plan choice, and we are currently reviewing these as we work to develop a final rule.

Alzheimer's Drug Coverage

Talking Points:

- Alzheimer's disease is a devastating illness that affects millions of Americans and their families. HHS is committed to helping people get timely access to treatments and improving care for people with Alzheimer's disease and their families.
- When evaluating new treatments for Medicare coverage, CMS is required to examine whether a medication is *reasonable and necessary*.
- There has not been an Alzheimer's treatment approved by the FDA on the basis of clinical benefit.
- Under the current coverage pathway, people with Medicare can access newly FDA-approved Alzheimer's medications through clinical trials.
- This allows people with early-stage Alzheimer's disease to access these drugs through Medicare, while additional evidence on the treatments' effectiveness in real-world settings is gathered.
- CMS will expeditiously review any new evidence that becomes available that could lead to a reconsideration and change in the current coverage framework.

If pressed on FDA vs. CMS decisions:

- FDA and CMS have different legal authorities to use when considering product approvals, for FDA, and coverage, for CMS. The FDA makes approval decisions based on whether a product is safe and effective while CMS makes coverage decisions based on whether something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- These two processes are separate and run independently by the two agencies. Importantly, however – unlike traditional approval – FDA's accelerated approval pathway does not require finding that a new product demonstrates clinical benefit based on a clinical measure (e.g. how a patient feels or functions) but instead on the effect on a surrogate endpoint that FDA determined reasonably likely to predict clinical benefit; in other words, granting accelerated approval does not provide CMS with absolute certainty that there will be a clinical benefit.

QUESTIONS:

Q: Why did CMS deny the Alzheimer's Association's request for an NCD consideration?

- There has not been an Alzheimer's treatment approved by the FDA on the basis of clinical benefit.
- CMS issued a Federal Register notice regarding the necessary criteria for a reconsideration. As these criteria were not met as of the time of the request, CMS denied Alzheimer's Association's request for an NCD reconsideration.

- CMS will continue to monitor the evidence and engage in discussions with all interested parties.
- CMS is committed to reviewing evidence supporting an NCD reconsideration.

Q: What are the differences in coverage decisions by Medicare for Aduhelm and lecanemab?

- There are no differences in the coverage decisions for Aduhelm and lecanemab.
- Currently, both Aduhelm and lecanemab have received accelerated approval from the FDA.
- If FDA approves Aduhelm, lecanemab, or any other anti-amyloid mAb based on a validated measure of clinical benefit, broader coverage using the current framework under Coverage with Evidence Development, would be available on the same day.

Q: Doesn't CMS believe the FDA does a good job? Why is CMS rethinking what FDA already decided?

- The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies.
- The FDA determines whether to approve a new medical product based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use.
- CMS can conduct its own independent review to determine whether an item or service should be covered nationally by Medicare, including examining whether it is reasonable and necessary for use in the Medicare population.

Q: Why is CMS continuing to refuse to cover new Alzheimer's drugs that have been approved by FDA and are now being covered by other federal programs including the Department of Veterans Affairs?

- It is our understanding that the U.S. Department of Veterans Affairs has issued important [exclusion and inclusion criteria](#) for its own coverage of this drug using statutory authorities that are different from what Medicare uses. By statute, CMS is required to make coverage decisions based on whether something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- ***If pressed:*** Because of the early evidence and the immense burden of this devastating disease on the Medicare population, the Medicare National Coverage Determination (NCD) provides coverage with evidence development to support rigorous studies to help answer whether this drug improves health outcomes for patients, and includes a coverage pathway for broader access to these drugs if they receive FDA

Q: When will CMS reconsider this national coverage determination (NCD) to determine whether these treatments/drugs are reasonable and necessary? How long would it take to reconsider this NCD?

- If new evidence emerges that addresses all outstanding questions, as outlined in the NCD, CMS will move swiftly to review and consider whether a reconsideration is warranted.
- ***IF PRESSED ABOUT THE NCD PROCESS:*** In the case of the Alzheimer's accelerated approvals, CMS determined a national coverage determination was needed because the current evidence shows that, while there may be the potential for clinical benefit, there is also the potential for serious harm to patients. (This harm may range from headaches, dizziness, and falls, to other potentially serious complications such as brain bleeds.)

Q: Why was the NCD process applied to this drug and not to other accelerated approvals for oncology drugs, which also have risks?

- CMS follows a long-standing process developed by Congress to determine whether a medical item or service (e.g., device, drug, preventive service) is reasonable and necessary for the diagnosis of and/or treatment of an illness or injury in the Medicare population.

Q: Have you used the NCD process before for other drugs?

The NCD process is defined in statute (section 1862(l) of the Social Security Act) and is generally how Medicare considers requests for coverage of new items and services. One recent example of CMS's use of the NCD process is for coverage of CAR T-cell therapies.

Q: Has CMS used the coverage with evidence development determination for other drugs or devices?

Yes, CMS has finalized over 20 coverage with evidence development (CED) NCDs.

ARPA-H

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
ARPA-H	1500	2500	+1000
Total Program Level	1500	2500	+1000

TALKING POINTS:

- The FY 2024 request for ARPA-H includes \$2.5 billion, an increase of +\$1 billion, to build on the success of the agency and continue progress towards achieving the President's vision.
 - The requested funding will support the recruitment of additional Program Managers and will support projects in key technical focus areas to drive transformational innovation in health and speed the application and implementation of health breakthroughs.
- We are thankful to Congress for permanently authorizing ARPA-H and for the work that Dr. Wegrzyn has done since arriving in October. One of the authorities bestowed on the agency by Congress allows them to actively recruit the best minds to tackle the hardest problems in health. ARPA-H will continue to aggressively recruit talented program managers and build a portfolio of programs across the health innovation landscape.
- ARPA-H now has its first technical team leaders in place, and they anticipate hiring approximately 15 Program Managers by the end of the year. Looking into FY 2024, the agency anticipates doubling the number of Program Managers and programs.

QUESTIONS:

- **Q: Where will ARPA-H be located?**
- ARPA-H recently announced their intention to establish sites in three different geographic locations, in accordance with legislation.
- In order to fulfill the agency's mission and the President's vision, ARPA-H must seek the best ideas from all over the country, and serve all Americans, wherever they may be.
- Unfortunately, access to healthcare and innovation can be challenging for Americans, depending on the geography where they are located.
- ARPA-H embraces the opportunity to expand beyond a single location, and intends to use the three sites to accelerate transformational breakthroughs in health by directly connecting ARPA-H with stakeholders, customers, investors, and transition partners.

- The first site will focus on stakeholders and operations and will be established in the Washington, DC area. This will put ARPA-H near key stakeholders, Congress, HHS, CMS, FDA, NIH, the White House, and other federal partners that are essential to their mission.
- Having a location near the majority of our nation's regulatory and legislative partners is crucial.
- In addition to this location, ARPA-H will also be seeking proposals to identify two sites in different regions of the U.S.
- The remaining two sites will serve as hubs, forming the foundation of a hub-and-spoke health innovation network, which will feature numerous spokes across the United States.
- Selection for these remaining two sites will be through an open and competitive process open to any geography in the U.S.
- ARPA-H will not compete the location of the Stakeholder and Operations hub site, but will rely on standard GSA and leasing processes to identify a suitable site.
- ARPA-H will have a nationwide network and part of that network will be in D.C. it is only one of their sites, they will have 3 hubs total each with important roles to fill for the agency.
- No matter where the agency is physically located, its funding will support the best and brightest ideas across the country.

Q: ARPA-H has received \$2.5 billion over the last two fiscal years, we are concerned they will not be able to obligate such an increase, are you confident they will be able to?

- The Department and the Administration fully supports achieving the President's vision for ARPA-H and realizing transformational change and accelerating health outcomes for everyone. Since Dr. Wegrzyn was sworn in as the inaugural director in October, the agency has made tremendous progress. Congress permanently authorized the agency and provided a +50% increase in appropriated funding for its second year in existence. During the first quarter 2023, ARPA-H hired their first program managers and expect programs to begin shortly. The agency has already established operations across all functional areas, hired more than 100 professionals with extensive experience across the health, science, and technology landscape, and met with hundreds of stakeholders from patient advocates to providers to investors. The agency has done all this in just a few months and is in a place where they are ready to hit the ground running to achieve their mission.

Q: How will ARPA-H stay independent from NIH?

- ARPA-H and NIH are complements with one another and both are members of the health innovation ecosystem. ARPA-H and NIH funding is invested in different types of innovation. ARPA-H looks to address health problems that cannot be readily

accomplished through traditional research or commercial activity. Both agencies have the goal of improving the health of everyone but will achieve that with different methods.

- It is also important to note that ARPA-H is a stand-alone entity and is not a NIH Institute or Center, and will not be located on the NIH Campus. While the Consolidated Appropriations Act of 2023 places ARPA-H within the NIH, the ARPA-H Director reports directly to me and the ARPA-H budget is also separate from NIH.

Behavioral Health

(Dollars in Millions) Discretionary Funding

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	5	5	--
HRSA	2,034	2,500	+466
IHS	394	473	+79
CDC	1,132	1,814	+682
NIH ²	8,199	8,382	+183
SAMHSA	7,518	10,422	+2,904
AHRQ	8	20	+12
CMS (discretionary)	5	8	+3
Total Discretionary Program Level	19,295	26,625	+4,330

¹ The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year.

² The FY 2023 Enacted and FY 2024 amounts are estimates and subject to change as NIH finalizes internal allocations.

TALKING POINTS:

- This budget invests \$4 billion more in discretionary funding in meeting behavioral health needs, including funds to increase access to crisis services and grow the behavioral health workforce.
- Suicide is the second leading cause of death for people between ages 10 and 34. The budget includes \$836 million to the 988 and Behavioral Health Crisis program, an increase of +\$334 million, to ensure capacity for the Lifeline to provide life-saving **crisis services** to the estimated 9 million 988 contacts in 2024.
- The budget invests in the **behavioral health workforce** by supporting an estimated 27,000 total mental health and substance use disorder trainees and providers. Specifically, the budget proposes \$387 million for Behavioral Health Workforce Development Programs, an increase of +\$190 million, to grow the number of behavioral health professionals through training approximately 18,000 behavioral health providers; such as psychiatrists, psychologists, clinical social workers, marriage and family therapists, counselors, and peer support specialists.
- Certified Community Behavioral Health Clinics provide high quality, cost-effective **behavioral health services** when and where patients need them. With \$20.1 billion in Medicaid matching funds over 10 years, the budget converts the existing demonstration into a permanent option.

QUESTIONS:

Q: How does the budget address the youth mental health crisis in the United States?

- We have seen a significant increase in mental health needs among youth, including depression, anxiety, and suicidal ideation. The budget includes investments in several programs addressing youth mental health, including Project AWARE, the National Child Traumatic Stress Network, and the Children's Mental Health Services program.
- The nation's mental health crisis is also disproportionately impacting our most vulnerable youth. In 2021, lesbian, gay, and bisexual youth reported greater levels of poor mental health. The budget request for the 988 Lifeline will support specialized services for LGBTQI+ youth to ensure tailored services for this important population.

Q: Some populations are at higher risk of behavioral health concerns—how does the budget focus investments on communities that need it most?

- Suicide risk is disproportionately high for tribal populations, sexual and gender minorities, middle-aged adults, and veterans. The budget proposes a significant increase for the 988 Lifeline, which includes supports for LGBTQI+ youth and services for Spanish speakers. The budget also includes an increase within the Indian Health Service to provide services to American Indian and Alaska Native patients, including suicide prevention, treatment for substance use disorder, and both in person and tele-behavioral health services.
- Individuals with a mental illness are also more likely to experience homelessness than those without mental illness, and they experience homelessness longer than the rest of the homeless population. The budget proposes to provide \$110 million for SAMHSA's Projects for Assistance in Transition from Homelessness program, an increase of +\$43 million above FY 2023 enacted, to expand the number of communities served and substantially increase the number of participating providers, resulting in 212,000 individuals contacted and 119,000 individuals enrolled in FY 2024.

Q: To improve access to care, the nation needs more behavioral health providers. How does the budget address this need?

- HHS is committed to advancing the recruitment, training, and supporting a diverse behavioral health workforce. The budget includes \$37 million for SAMHSA's Minority Fellowship Programs, an increase of \$17 million over FY 2023 enacted, to almost double the number of fellows. The budget proposal includes a new service requirement to ensure Fellowship participants are supporting communities in need. The budget also proposes historic investments in HRSA to support further expansion of the behavioral health workforce.

Q: How does the budget improve mental health parity?

Medicare beneficiaries with mental health and substance use disorders are just as deserving of protection and care as those with medical, physical, or surgical needs. Unlike most private and employer-based insurance and Medicaid plans, Medicare is not subject to the 2008 Mental Health Parity and Addiction Equity Act, which requires health plans that offer mental health and substance use disorder benefits to provide coverage on par with the medical and surgical benefits they offer. Applying parity to Medicare will ensure that Medicare behavioral health benefits do not face greater limitations relative to medical and surgical benefits. The budget invests \$1.2 billion in HHS funding to strengthen mental health parity on the private insurance market by requiring all plans to cover mental health and substance use disorder services, eliminating loopholes that have resulted in disparate coverage practices, and requiring plans to cover three behavioral care visits with no beneficiary cost sharing.

Q: How does the budget improve behavioral health integration?

- Behavioral investments throughout the budget support integration efforts. Just to name a few specific proposals:
 - \$103 million, an increase of \$47 million, for SAMHSA's Primary and Behavioral Health Care Integration program, to advance the integration of physical and behavioral health care using evidence-based models of care.
 - \$90 million, an increase of \$52 million, to allow to CDC scale up the *What Works in Schools* program from 28 up to 75 local education agencies nationwide. This program strengthens the integrated delivery of mental health promotion and treatment interventions to students and families across a range of care settings.
 - \$5 million in funding for AHRQ to research and understand how to scale existing Local Integrated Care Network models – which provide behavioral health support systems for primary care practices.

Bipartisan Safer Communities Act (BSCA)

TALKING POINTS:

- The Bipartisan Safer Communities Act (BSCA) which was signed into law by President Biden last summer strengthens the mental health care system, school safety programs, and gun safety laws – further advancing the President's whole-of-government mental health strategy, which he launched as part of his Unity Agenda.
- HHS has worked hard to get funding in the bill out the door as quickly as possible.
 - See Grant Award funding below.

If asked about grant funding:

- BSCA provided \$800 million in funding to SAMHSA for behavioral health grants, including:
 - \$250 million for Community Mental Health Services Block Grants,
 - \$240 million for Project Advancing Wellness and Resiliency in Education (Project AWARE),
 - \$120 million for Mental Health Awareness Training,
 - \$40 million for the National Child Traumatic Stress Network
 - \$150 million for the new 988 Suicide & Crisis Lifeline.
- All BSCA funding for the 988 Lifeline has been obligated.
- HRSA announced \$60 million in Primary Care Training and Enhancement awards and \$15 million in Pediatric Mental Health Care Access awards, with more to come.

If asked future opportunities:

- The law includes a nationwide expansion of Certified Community Behavioral Health Clinics (CCBHCS).
 - We recently awarded planning grants to 15 states.
 - After one year of state planning, they are expected to apply to participate in the demonstration program funded through Medicaid, and 10 states will be selected to start as soon as July 2024.
 - Ultimately, every state will have the opportunity to participate.
- CMS is working to:
 - Award \$50 million in grants towards implementing, enhancing, or expanding the provision of assistance through school-based entities under Medicaid or CHIP.
 - Provide guidance and technical assistance on Medicaid telehealth services.
 - Review State Implementation of Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services.

Cancer Moonshot

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	2	50	+48
HRSA	11	21	+10
IHS ²	--	108	+108
CDC	656	839	+183
NIH ³	216	716	+500
Total Program Level	885	1,733	+849

1/ The FY 2023 President's Budget proposed a one-time increase of \$20 million for FDA's cancer moonshot activities. The funds were requested with three-year availability. The House mark provided \$7M as an annual base increase and not as a one-time increase.

2/ The FY 2023 Budget and all FY 2024 columns propose IHS funding as mandatory.

3/ Funding level reflects authorized CURES and non-CURES funding

TALKING POINTS:

- The reignited Cancer Moonshot includes the specific aim of **cutting the cancer mortality rate in half within 25 years**.
- We will build upon the successes of the foundational Moonshot programs (e.g., improving immunotherapy for adult and pediatric cancers, exploring drug resistance, boosting efforts for collecting/sharing cancer data) to continue to improve prevention, diagnosis and treatment outcomes and quality of life for all people.
- In February we hit the one-year anniversary of President Biden's Cancer Moonshot Initiative. Key efforts to date include:
 - **Increasing Cancer Screenings in Underserved Communities:** In February HRSA awarded nearly **\$11 million to 22 health centers** to improve access to life-saving cancer screenings and early detection services for underserved communities. These awards double support for an initiative launched last year by the Biden-Harris Administration through which HRSA-funded health centers are working to close the cancer screening gap and decrease the impact of preventable cancers.
 - **Expanding NCI Clinical Trials:** This will allow the development of new and improved treatment options for people with cancer through novel clinical trials; We will also ensure that cancer clinical trials are available in the communities in which people live and receive their care.
 - **Establishing comprehensive infrastructure to share and process cancer data** and enabling the fullest possible use of all forms of research data while protecting patient privacy.

QUESTIONS:

Q: What is different about investments this time?

- The Obama-Biden administration delivered significant investments in cancer research activities that accelerated progress of prevention, diagnosis, and treatment programs.
- Because of this foundation, this Administration is now able to set the goal of reducing the death rate from cancer by at least 50 percent over the next 25 years.
- The President has now emphasized the need to focus on patients and their families living with cancer, a focus of HHS investments. We will continue to make foundational investments in cancer research, prevention, and care.
- We are investing in outreach and education efforts with \$20 million to support HRSA-funded health centers in reaching underserved communities and part of FDA's \$50 million Cancer Moonshot funds dedicated to research and education.

Q: What is NIH doing to diversify Clinical Trials?

- NIH remains dedicated to ensuring inclusion throughout its supported clinical research activities.
- NIH has longstanding policies to ensure appropriate inclusion of women and minorities, and individuals across the lifespan in clinical research.
- NIH has made several strides to ensure that clinical trials reach as many communities as possible and that we are held accountable for continuing these efforts. For example,
 - 29% of U.S. participants in NIH-funded clinical research identified as members of a racial or ethnic minority group (FY22 74% identified as white, 1.3% unknown, unreported).
 - Female participants represented 52%.
 - Children under 18 years represented 14% and adults older than 65 represented 21%.
- To facilitate greater diversity in clinical trials, it is crucial to establish and facilitate trust between the research community and local community members and leaders.
 - Lessons learned from the Community Engagement Alliance (CEAL) program which helped engage communities around COVID-19 are being applied to broader research contexts.

Q: What are you doing to address multi-cancer early detection?

- One year ago, President Biden reignited the Cancer Moonshot and set new national goals to cut the death rate from cancer by at least 50% over the next 25 years and improve the experience of people and their families living with and surviving cancer.
- At HHS, we are doing all we can to make cancer prevention and screening services accessible to everyone in the United States, including taking action to address the estimated 9.5 million cancer screenings missed during the pandemic.
- I look forward to hearing more from you about increasing access to preventive health services, particularly for cancer prevention.
- HHS always appreciates the opportunity to provide technical assistance to Congress on important health care issues.

CCBHCs
(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Certified Community Behavioral Health Clinics (SAMHSA)	\$385	\$553	+\$168
Total Program Level (Discretionary Only)	\$385	\$553	+\$168

TALKING POINTS:

- The Certified Community Behavioral Health Clinic (CCBHC) model is designed to ensure access to coordinated and comprehensive behavioral health care. CCBHCs are required to serve anyone who requests care for mental health or substance use, regardless of their ability to pay, place of residence, or age - including developmentally appropriate care for children and youth.
- The Bipartisan Safer Communities Act provided funding to give every state the opportunity to participate in CCBHC demonstration program already successfully running in nine states. Fifteen states were recently awarded planning grant funding from the law, with more to come.
- The FY 2024 Budget converts the CCBHC demonstration to a permanent program and proposes a +\$168 million increase for SAMHSA's CCBHC program.
- This investment into CCBHCs underscores the Biden-Harris Administration's commitment to strengthening the mental health of all Americans, including people living in our nation's most vulnerable communities. Behavioral health is health. Period. There should be no distinction. This investment will bring us closer to that reality.

QUESTIONS:

Q. How are state planning grants different from the CCBHC expansion grant program?

- State planning grants will help states prepare to participate in the CCBHC program funded through Medicaid. SAMHSA's CCBHC Expansion grants are awarded directly to provider organizations.
- The purpose of the provider-level CCBHC Expansion grant is to support clinics to meet the CCBHC certification criteria and mainly support service development and delivery.

Q. How do the state planning grants work?

States that have completed planning grants will be eligible to apply to participate in the CCBHC Demonstration at the end of the year-long planning grant period.

Q. Can states that received planning grants in FY 2016 apply again in this round?

States that received planning grants in FY 2016, but were not selected to participate in the Medicaid Demonstration, can re-apply.

Q. How will states be selected for planning grants?

States' grant applications will be peer-reviewed, scored, and selected based on: statement of need, population of focus, proposed approach, staff and organizational experience, and data collection and performance measurement.

Q. What happens after the planning grant project period ends?

At the end of the planning grant period, participating states must submit their applications to join the CCBHC Demonstration for a four-year period starting on July 1, 2024.

CDC Moving Forward

TALKING POINTS:

- CDC Director Dr. Rochelle Walensky launched Moving Forward to strengthen CDC by strategically building on lessons learned during the COVID-19 pandemic to break down silos, reduce bureaucracy, and improve accountability.
- This effort will be critical to deliver health information more clearly and quickly to policy makers and American. We're already seeing the benefits of this effort:
 - CDC was the first in the world to produce data showing real-world effectiveness of the JYNNEOS vaccine for mpox.
 - Two public-facing databases went live in April 2022 that provide public health practitioners and the public with critical data about non-fatal overdoses and overdose deaths to tailor interventions in their communities.
- As CDC makes the changes it can internally, we also need help from Congress through funding and new authority to fully deliver on its mission of protecting the health, safety, and security of Americans.

QUESTIONS:

Q: Should Congress Authorize CDC and put in statute a clear organization structure?

- I want to be clear that CDC activities are authorized in the Public Health Service Act.
- Through Moving Forward, CDC has focused on lessons learned and is making important changes to break down silos, reduce bureaucracy, and improve accountability.
- As CDC makes the changes it can internally, we have also identified key policy changes that can only be achieved through Congress.
- My hope is that we can focus on these key areas to find bipartisan solutions to support the health, safety, and security of Americans.

Q: How will the reorganization allow CDC to better serve the American people?

- Reduce bureaucracy and improve accountability.
 - CDC elevated the offices of science, laboratory, and data to be in the Office of the Director.
 - These are cross-cutting offices that provide foundational support and should have direct access to the Office of the Director.
 - CDC combined two centers that supported relationships with jurisdictions, as well as workforce and infrastructure technical assistance.
 - This new center will provide clarity on where STLT should go for technical assistance and strengthen our working relationships with jurisdictions.

- CDC elevated the Center for Preparedness and Response to the Office of the Director.
 - Response activities cut across CDC and are not siloed to one center.

Q: What changes has CDC already made?

- Share science and data faster
 - Improved timeliness of getting science out by reducing internal review times by 50 percent.
 - We were the first country in the world to produce data showing real world effectiveness of JYNNEOS.
- Translate science into practical policy
 - CDC's Overdose Data to Action (OD2A) databases
 - These two, public-facing dashboards include near real-time syndromic data on nonfatal overdoses in emergency departments as well as information on the circumstances and context of overdose deaths. The dashboards allow public health practitioners and members of the public with critical data to tailor interventions in their communities.
- Develop a CDC workforce ready to respond to future threats
 - Established CDC Ready Responder Program.
 - This program, deployed in December, is identifying, training, and assigning staff to response roles, to better serve partner organizations, and protect communities that are most at risk during emergencies.

Q: What does CDC need from Congress?

- A modernized data authority to receive and share back data more quickly. This allows CDC to forecast, track, and prevent the spread of emerging issues.
- Workforce authorities – numerous workforce authorities to build and support CDC's workforce to quickly respond and to sustain that response through a public health emergency.
 - Direct Hire
 - Overtime and danger pay
 - Tax waiver for loan repayment
 - Non-competitive conversion for term hires
 - Ready Response – budget flexibility to have a cadre of responders ready to go at a moment's notice.
- Vaccines for Adults
 - We must leverage what we built for COVID to create a sustainable adult vaccine infrastructure to be better prepared for the next pandemic and to improve vaccine access and equity across our population.

Countermeasures Injury Compensation Program (CICP)/Vaccine Injury Compensation Program (VICP)

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		President's Budget	+/- FY 2023 Enacted
Countermeasures Injury Compensation Program	7,000	15,000	+8,000
Vaccine Injury Compensation:			
Vaccine Injury Compensation Trust Fund (HRSA Claims)	256,370	261,497	+5,127
VICTF Direct Operations - HRSA	15,200	26,200	+11,000
Subtotal, Vaccine Injury Compensation	271,570	287,697	+16,127

TALKING POINTS:

- First, COVID-19 vaccines are the most safe and effective way to prevent yourself from severe harm and death from COVID-19.
- Second, HHS is actively working to process claims as **quickly** as possible, in compliance with the relatively **high standard** set out in statute that must be met for compensation.
- While the Agency has worked hard to hire additional medical reviewers and is implementing key process improvements, the additional resources in the Budget will help support the work to **address the backlog**.
- The President's Budget request is a step in the right direction.

QUESTIONS:

Q: If we meet your budget request this year, will it resolve the current CICP backlog, and how quickly? What else is needed?

- Last year's Budget proposed \$15 million to review additional CICP claims and compensate eligible individuals. However, only \$7 million was appropriated which supported the hiring of additional staff.
- The additional funds we are requesting this year would help expedite the processing of claims by hiring additional medical reviewers, streamline the review process to be more claimant friendly, and compensate claims.

Q: What is the impact of the end of the COVID-19 Public Health Emergency on COVID-19 claims in the CICP?

The PREP Act Declaration for Medical Countermeasures against COVID-19 currently extends through October 1, 2024

Climate Health and Environmental Justice

TALKING POINTS:

- HHS is committed to addressing the impact of climate change on Americans' health and promoting climate resilience in the health care sector.
- As extreme heat events and hurricanes become more intense due to climate change, we need to understand and mitigate these impacts so our health systems are prepared.
- We also must make sure we are targeting our resources equitably to ensure that benefits accrue to communities that have been marginalized or overburdened by climate and environmental health hazards.

QUESTIONS:

Q: Why does HHS need an Office working on climate change? Doesn't EPA have health in their mission?

- Climate change is affecting our health today and putting lives at risk.
- Extreme heat events are predicted to happen more often and last longer due to our changing climate.
 - FACTOID: This past summer in Maricopa County, Arizona, [378 people died from heat](#). That number was up from the previous summer when [338 people died from heat](#).
- Hurricanes are becoming more intense due to climate change.
 - FACTOID: Hurricane Ian led to [at least 144 deaths](#) in Florida when it hit in September 2022, making it one of the worst hurricanes in state history. Two-thirds of the 144 confirmed deaths were people aged 65 years and older.
- While EPA has a role in protecting the environment and promoting public health, HHS is responsible for ensuring the resilience of our nation's healthcare systems.

Q: Is creating a new Office focused on climate change going to further strain our already overwhelmed healthcare systems?

- The recent heat dome event in Oregon and Washington and Hurricanes Ida, Ian, and Michael in Florida have shown us that the increasingly frequent and severe weather events caused by climate change are already causing hospitals to close and leading to illness and death.
 - FACTOID: Hurricane Ida [forced three damaged hospitals in Southeast Louisiana to evacuate 160+ patients](#). A massive failure of the electric grid forced hospitals to operate on generator power and rely on water from on-site wells.
- Failing to acknowledge and address this reality will only cause more harm to our most vulnerable citizens.

- The Office of Climate Change and Health Equity is already providing technical assistance and connections to existing federal resources to help health systems manage their growing risks associated with climate change.

Q: Congress hasn't given HHS any authority to regulate greenhouse emissions...why are you forcing Hospitals to reduce their emissions?

- The US health sector is responsible for roughly 8.5% of the nation's total greenhouse gas emissions. We are excited that over 830 hospitals have signed the White House/HHS Health Sector Climate Pledge to: cut their greenhouse gas emissions by 50% by 2030 and achieve net-zero emissions by 2050.
- With that said, the pledges made are voluntary; the organizations that signed this pledge are not obligated to report data on their progress to the federal government in association with this pledge.
- As I said from the moment we launched the Office, nothing is off the table when it comes to the policy levers the Department will deploy going forward. We will consider everything at our disposal and that could include regulatory action in the future.

Q: Why does HHS need its own Office of Environmental Justice? Aren't these issues covered under EPA and other departments?

- Protecting our nation's health from environmental harms requires working in partnership across government.
- Studies demonstrate that people of color and disadvantaged, vulnerable, low-income, marginalized, and indigenous populations are disproportionately burdened by environmental hazards.
- These populations are often exposed to unhealthy land uses, poor air and water quality, dilapidated housing, lead exposure, and other environmental health threats that drive health disparities.
- HHS has a key role in providing public health leadership and focusing human services to help meet the needs of these communities.
- One more point for a tangible example:
 - We're using the new Environmental Justice Index, developed by CDC/ATSDR, to show the cumulative burden of social, environmental, and underlying health factors in neighborhoods that would bear the brunt of transportation projects. For example, a tolling program in Manhattan that could increase air pollution in the Bronx should maximize health protections for already vulnerable communities.

Q: Our understanding is that both the Office of Climate Change and Health Equity and its Environmental Justice division have already been established. Congress did not appropriate funding for this Office in FYs 21, 22, or 23. From what resources has HHS funded the operations of this Office?

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- I have determined that based on the importance of this work, my Secretarial Initiatives and Innovations funding would be used to support this work while we await dedicated Congressional funding.

CMMI /Innovation Center

TALKING POINTS:

- Innovation in health care should be designed for the people it serves; its success should be measured by how well it improves health, experience, and affordability of care.
- The Innovation Center, with its federal and community partners, has started building the foundation toward a health system that achieves equitable outcomes through high-quality, affordable, person-centered care.

New Coordinated Care Models

- The Innovation Center has announced the:
 - Enhancing Oncology Model (EOM), which aims to bring enhanced services and coordinated care to people with cancer; and
 - The redesigned (ACO REACH) Model, which aims to increase access to team-based, coordinated care, and improve the beneficiary experience, especially for underserved populations

New Drug Models

- This year, I selected three new models for testing by the CMS Innovation Center to help lower the high cost of drugs, promote accessibility to life-changing drug therapies, and improve quality of care. This report responds to President Biden's Executive Order 14087, "Lowering Prescription Drug Costs for Americans," which complements the historic provisions in the Inflation Reduction Act of 2022 (IRA) that will lower prescription drug costs.

QUESTIONS:

Executive Order

Q: Why is CMS maligning drugs that rely on surrogate end points – and the accelerated pathway used by FDA? The drugs approved under this process clearly show pre-clinical benefit.

- The Accelerating Clinical Evidence Model does not change the FDA accelerated approval process. The model simply aims to incentivize timely completion of confirmatory trials.
- Completion of confirmatory trials is important so that everyone has the benefit of better understanding the value of these accelerated approval drugs.
- The Accelerating Clinical Evidence Model will not change FDA's role in determining and assessing whether a drug has met the drug approval standard or whether a confirmatory trial confirms clinical benefit.

Q: Congress just updated the FDA user fee law. Can you tell me more about how CMS proposes to define "too long" for a confirmatory clinical trial to conclude?

CMS will cooperate with the FDA as we develop this model and will clearly define expectations regarding the completion of clinical trials.

Q: Many plans have copayments less than \$2 on generic drugs currently. Won't this just create upward pressure on all plans to charge \$2, thus increasing copays for beneficiaries?

- This model would encourage plans to expand their current low copay drug offerings and provide beneficiaries access to a standardized list of generics (with copays of no more than \$2) across participating plans. Historically market dynamics have shown Part D sponsors want to offer competitive cost-sharing.

ACO REACH

Q: Concerns have been raised regarding the participation of organizations with known histories of fraud and abuse in the ACO REACH Model. How will CMS prevent these organizations from engaging in fraud and abuse under the ACO REACH Model?

- CMS conducts a comprehensive set of vetting, monitoring, auditing, and analytic activities under the ACO REACH Model aimed at protecting beneficiaries, and the fiscal health of the Medicare program. Each model participant is required to cooperate with CMS's monitoring and auditing activities, and each must require its downstream providers and suppliers to cooperate with those activities as well.
- Failure to comply with model requirements is addressed through a set of escalating remedial actions that include placement on a corrective action plan or, in select instances, termination from the model. In addition, CMS may refer possible violations of federal laws by model participants to other federal agencies, such as the Department of Justice.

Q: Are any of the REACH ACOs health insurers or Private Equity / Venture Capital backed? If so, how many?

- Based on available data, CMS estimates that less than 10% of REACH ACOs are affiliated with a parent organization that also operates health insurance plans.
- To bring greater transparency to this program, CMS committed to publicly releasing ownership data on its participants and did so earlier this year.
- CMS also made requirements of participants' governing boards, ensuring 75% of the board is made up of doctors and health care providers and requiring participation by beneficiaries and their advocates.

Q: Participants in the Global and Professional Direct Contracting Model were able to transition to ACO REACH without having to go through the applicant screening process. Did CMS review existing participants against the new applicant screening process?

- To be able to transition to the ACO REACH Model, Global and Professional Direct Contracting Model participants were assessed on the status of their compliance the current model requirements.
- They were also required to submit additional documentation consistent with what CMS required of ACO REACH Model applicants, specifically ownership, leadership, and governing board documentation that was used as part of a comprehensive vetting process.

Conscience Protections

TALKING POINTS:

- HHS has long enforced federal conscience and religious nondiscrimination laws for many decades.
- HHS will continue to follow the law and enforce it, which importantly includes religious freedom and conscience laws.

QUESTIONS:

Q: Does OCR's recent reorganization mean OCR will abandon enforcing conscience laws and religious freedom protections?

- No. HHS will continue to follow the law and enforce it, which importantly includes religious nondiscrimination and conscience laws.
- The reorganization re-integrates the Office for Civil Rights' expertise in protecting conscience and the free exercise of religion into the overall civil rights responsibilities of the division to bridge an unnecessary separation between these authorities.
- The change restores a holistic approach to civil rights enforcement while also providing more effective use of available staff expertise and resources.

Q: Will the Conscience NPRM be impacted by this reorganization?

- No, the reorganization will not impact OCR's work on the Conscience NPRM.
- This NPRM proposes to restore the longstanding process for the handling of conscience complaints and provide additional safeguards against conscience and religious discrimination.
- OCR is currently reviewing comments received earlier this month.

Q: What is the breakdown of OCR's complaints by authorities?

- OCR's caseload has multiplied in recent years. In CY 2021, OCR received approximately 51,280 complaints, 27% alleged violations of civil rights, 7% alleged violations of conscience/religious freedom (either singularly or in combination with other civil rights allegations), and 66% alleged violations of health information privacy and security laws. HIPAA violations make up the majority of complaints received by OCR and this will only continue to grow.

Q: What outcomes does HHS hope to achieve through this realignment?

- OCR enforces 55 statutory authorities. OCR realigned the Division's activities to better meet its statutory mandates, enforce the law and be responsive to the growing needs of the public in health information privacy, data, and cybersecurity, conscience protections, and civil rights. These changes move OCR from a more siloed operation to one that

utilizes the agency's skill set and resources more effectively. Specifically, OCR reorganized the responsibilities of the current Health Information Privacy, Operations and Resources, Civil Rights and the Conscience and Religious Freedom divisions into new functional crosscutting areas: for Policy, Strategic Planning, and Enforcement where staff work in their areas of expertise based on skill set to drive greater implementation and enforcement of the law.

COVID Supplemental Funding Balances

(Dollars in Billions)

Supplemental	Enacted	Remaining Balance	Percent Remaining
Coronavirus Preparedness and Response Supplemental	\$6.5	\$0.5	7%
Families First Coronavirus Response	\$1.3	\$0	0%
Coronavirus Aid, Relief, and Economic Security	\$142.5	\$3.1	2%
Paycheck Protection Program and Health Care Enhancement	\$100	\$7.2	7%
Coronavirus Response and Relief	\$73.8	\$1.3	2%
American Rescue Plan	\$160.5	\$17.3	11%
Total Supplemental Funding	\$484.6	\$29.5	6%

TALKING POINTS:

- Since 2020, we've delivered over 294 million vaccines, collaborated with the U.S. Postal Service to distribute more than 670 million at-home tests, administered over 22 million vaccine doses at our HRSA-supported health centers, and continuously reviewed, updated, and communicated new guidance to the public and our health care industry partners.
- As of March 6, HHS has obligated 94% of the COVID supplemental funding received; that's over \$455 billion to purchase vaccines and other critical medicines, reimburse providers for COVID care, distribute tests, conduct research, and otherwise protect the Nation's health.
- HHS has approximately \$29.5 billion left unobligated in COVID supplemental funding – only 6% of the of total we've received – with the remainder planned to support critical projects and in the process of execution.
- HHS's goal for these balances is the same goal we have for the FY 2024 budget: move forward from the COVID-19 pandemic, and look to the future by investing heavily in pandemic preparedness. We must do everything we can now to be ready for the future.

QUESTIONS:

Q: You'll be ending the Public Health Emergency for COVID in May. Will you be returning COVID funding balances to Congress now that there's no emergency?

- All balances are intended for critical, ongoing activities such as, monitoring the safety and efficacy of vaccines, conducting multi-year research and development on new medical countermeasures, and sustaining stockpiled countermeasures and protective equipment for the next emergency.
- These investments also support our public health preparedness infrastructure. CDC continues to invest supplemental funding at the federal, state and local levels to build our nation's capacity to respond to COVID-19, but also for other, future threats.

- We've seen a consequential impacts from the dollars spent to far on the response. Since 2020, we've delivered over 294 million vaccines, collaborated with the U.S. Postal Service to distribute more than 670 million at-home tests, administered over 22 million vaccine doses at our HRSA-supported health centers, and continuously reviewed, updated, and communicated new guidance to the public and our industry partners.

Q: COVID revealed the ways in which the United States was not ready for an infectious disease threat of this magnitude. What are you doing to ensure we can be better prepared for future biological threats and infectious disease outbreaks?

- We need to do more to prepare against potential biological threats – the question is “when”, not “if” the next pandemic threat will emerge.
- That's why my FY 2024 budget includes a \$20 billion plan to transform the way we prepare for and respond to pandemic and other biological threats. The looming avian influenza threat is exactly the kind of threat we could have been preparing for in advance – but we need funding to do so.
- The Budget also includes discretionary investments to preparedness complementary to the mandatory proposal. This includes \$400 million in new funding at ASPR to continuously invest in long-term pandemic preparedness capabilities, over \$1 billion for BARDA, \$995 million for the Strategic National Stockpile, and other strategic investments at CDC, FDA, and NIH.
- The budget also includes a suite of legislative proposals intended to give HHS and its agencies better authorities to prepare for and respond to emergencies. We learned many lessons during COVID, mpox, and other recent emergencies, but we need Congress's help to implement these changes.

Q: If you have almost \$30 billion dollars left, and my hospital that your agency denied Provider Relief Funds to is on the verge of closing due to lack of funds—why can't you re-open the PRF and give my hospital the funding it needs to stay open?

- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding —96% of all funding, with the remaining 4% in the process of being executed.
- HHS has allocated resources to reimburse health care providers for the cost of COVID-related health care through the Provider Relief Fund program. HRSA conducts a thorough, multi-step process to evaluate and verify provider claims and requests for reconsiderations. While most funds have been obligated, in some instances, HRSA's process is not yet complete. Congress made these funds available until expended.
- HHS obligates PRF funds as payments are made.

Q: Why are you using PRF dollars for vaccines and testing if you have \$30 billion left?

- All Covid supplemental funding has been allocated in alignment with the purposes of the appropriations. While approximately \$30 billion is unobligated, all of this amount is already allocated to critical needs, mostly to support actively ongoing projects, including for Provider Relief Fund payments. All remaining funding cannot be obligated at once – many of the ongoing projects, like clinical trials, require us to continue to provide funding over time.

Q: If you have \$30 billion why did you close the Uninsured Program?

- HHS is committed to doing everything it can to ensure that the uninsured can receive the lifesaving care, vaccines, and therapeutics that they need. The funding for the uninsured program has been exhausted, a fact we alerted Congress to many times as we requested additional COVID supplemental funds
- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding, which is nearly all of the PRF funding we received.
- While we do have \$30 billion in unobligated funding, all of this funding is allocated for critical needs. Additionally, not all unobligated funding would be legally available to support the Uninsured Program.
- Further, my administration is committed to insuring the un- and under-insured in this country, which is why the national uninsured rate hit an all-time low of 8% in 2022. To this same end, I call on the remaining 10 states to follow North Carolina's lead and expand their Medicaid programs.

Q: COVID-19 Tests.gov website shut down in 2022 due to a lack of funds, but now you have \$30 billion. Please explain this to me?

- Our groundbreaking partnership with the US Postal Service distributed more than 670 million at-home COVID-19 tests to Americans all across the country. By making tests freely available through multiple means, as well as life-saving vaccines and therapeutics, we've done everything we can to tackle the COVID-19 pandemic.
- HHS has approximately \$29.5 billion left unobligated in COVID supplemental funding – only 6% of the of total we've received – with the remainder planned to support critical projects and in the process of execution.
- HHS could not continue to distribute tests through covid.gov/tests with limited funding. The HHS response to COVID-19 is broader than just providing free tests, and we had to allocate resources to where they were needed most.

COVID - Long COVID

TALKING POINTS:

FY 2024 Budget Talking Points

- The Administration continues to invest in delivering high-quality care for individuals experience Long COVID, making services and supports available, and advancing the nation's understanding of Long COVID.
- To help improve Long COVID care, the budget proposes \$130 million in new resources to HRSA to:
 - Fund Long COVID Integrated Diagnostics and Care Units, which will provide integrated multispecialty evaluation and care for uninsured patients with Long COVID, including through telemedicine.
 - Support Provider Training, Capacity Building and Consultation, serving to provide primary care providers with the latest knowledge about Long COVID diagnostics and treatment.
- Additionally, the FY 2024 budget invests \$19 million, an increase of \$9 million, to continue AHRQ's work to ensure health care delivery systems are prepared to provide patient-centered, coordinated care. Long COVID cases can be complex, affecting multiple organ systems and touch multiple specialties.

General Long COVID Talking Points

- Most people who have COVID-19 recover quickly and completely, but some people continue to experience new or re-occurring symptoms or conditions for weeks, months or even years after the initial infection.
- We must build on the lessons learned from other infection associated chronic illness, such as ME/CFS or dysautonomia.
- The end of the declared Public Health Emergency will not signal the end of the COVID-19 pandemic. Long after the more immediate effects of the pandemic, the longer-term impacts on the health of the nation will continue for years to come. The scale of Long COVID morbidity and mortality and the breadth of its clinical manifestations represent an unprecedented, but not insurmountable, challenge.
- Pandemic preparedness must include planning for post-infectious chronic illness.
- To meet our public health goals there must be continued investment at the federal and community level to meet people in need where they are, and to provide support and services to help them live their healthiest lives.

Federal Government Response to Long COVID

- The U.S. government has been conducting research on Long COVID since 2020 and providing care for individuals with Long COVID within federally supported healthcare systems such as the Veterans Health Administration, Federally Qualified Community

Health Centers, Certified Community Behavioral Health Clinics, and the Indian Health Service.

- o Milestones in the U.S. government response include a call for action on Long COVID in the [Presidential Health Equity Task Force](#), Final Report and Recommendations, released in October 2021, [announcement of the landmark RECOVER study in February 2021](#), and inclusion of Long COVID in the [National COVID-19 Preparedness Plan](#) in March 2022.
- o In April of 2022 President Biden issued the [Memorandum on Addressing the Long-Term Effects of COVID-19](#) instructing the Secretary of Health and Human Services to begin coordinating a government-wide response. Part of that response resulted in the publication of two reports in August 2022. These reports were the product of collaboration among 14 federal departments and were a significant step in orchestrating a government wide response. Together, these reports use a whole-of-government approach and call on the power of public-private partnerships to provide relief for those affected by Long COVID.
- o The [Services and Supports for Longer-Term Impacts of COVID-19](#) Report outlines over 200 federally funded support and services that may be available for individuals experiencing the longer-term effects of COVID-19 in the areas of Long COVID and associated conditions, mental health, substance use, and bereavement.
- o The [National Research Action Plan on Long COVID](#) provides an overview of current U.S. government conducted or funded research and proposes a comprehensive and equitable research strategy to inform our national response to Long COVID.

RECOVER Initiative Talking Points:

- NIH launched the Researching COVID to Enhance Recovery (RECOVER) initiative in December 2021 to define the clinical symptoms, long-term outcomes, underlying biology of Long COVID, and safe and effective therapeutic and preventive interventions.
- NIH RECOVER built the world's largest, most diverse clinical cohort of Long COVID patients across the lifespan. The initiative is patient-centered and is unparalleled in scope, scale, and speed, with integrated analyses of EHR and other real-world data.
- We have learned vital information from RECOVER, including the clinical spectrum in adults and children, risk factors for developing Long COVID or new-onset conditions, the impact of variants and vaccination, and symptom profiles that will enable clinical practitioners to screen for Long COVID.
- RECOVER expects to launch a suite of clinical trials this year that will delve deeper into key symptoms and explore how the virus survives and leads to long-term symptoms. These studies will also help us to understand the underlying biology so we can fine-tune interventions moving forward.

QUESTIONS:

Q: Why haven't we seen results from RECOVER yet? When will those be publicly available?

- RECOVER is moving at an unprecedented quick pace for a study with the comprehensive national scale required to understand and treat a new syndrome. RECOVER is a longitudinal, multifaceted effort which has already yielded results identifying the clinical symptoms in children and adults, risk factors for PASC, the impact of variants and vaccination on disease. In addition to these successes, a suite of clinical trials is expected to be launched in summer 2023 to focus on the symptoms that are most burdensome to daily life and to look at disease mechanisms. Like any clinical trial, we would expect initial results from clinical within a few years, however longitudinal studies inherently require several years if not decades to complete.

Q: When will clinical trials for Long COVID begin? Why is it taking so long?

- To achieve the depth and breadth required to get the answers patients need, we did a great deal of the work on the front end—like developing master protocols—based on everything we know. This is helping us to get to answers faster with data we can depend on and use, and treatments patients can trust.
- RECOVER is launching multiple randomized, comparator-controlled clinical trials for which site recruitments are underway. Through the balance of this year, RECOVER will be testing candidate therapies for symptoms described by patients as being most burdensome. Those protocols are now posted to clinicaltrials.gov.

Q: What is HHS doing to respond to Long COVID?

- Nearly a year ago the Biden Administration issued the Memorandum on Addressing the Long-Term Effects of COVID-19 which tasked me with organizing the Government-Wide Response to the Long-Term Effects of COVID-19. Including the issuance of two reports:
 - o **The Services and Supports for Longer-Term Impacts of COVID-19 Report (Services Report).** The Services Report outlines over 200 federally funded supports and services for individuals experiencing the longer-term effects of COVID-19 in the areas of Long COVID and associated conditions, mental health, substance use, and bereavement.
 - o **The National Research Action Plan on Long COVID (the Research Plan).** The Research Plan outlines over 70 active research programs on Long COVID, including NIH's RECOVER and CDC's INSPIRE, which have helped contribute to the hundreds of publications, with more on the horizon. The Research Plan also proposes a comprehensive and equitable research strategy to inform our national response to Long COVID.
- Starting work in earnest in mid-2021, the U.S. government continues to lead and make advancements in research and provide resources to those affected by Long COVID, recognizing much more must be done to support people experiencing Long COVID and associated conditions.

Q: I hear from constituents that they go to the doctor and nobody believes them and they can't get care. What is HHS doing to fix this?

- Unfortunately, this occurs. While there are many compassionate and competent healthcare providers finding and caring for Long COVID patients, it is a new entity and awareness needs to increase both among the citizenry and healthcare professionals.
- Our whole-of-government coordination efforts to address the long-term effects of COVID-19 has prioritized listening to and learning from those with lived experience, so we can accelerate understanding and breakthroughs together.

- Admiral Levine, the Assistant Secretary for Health, has met with Long COVID patients, providers, and researchers to hear more about their experiences and how we can harness the federal government's strengths to address their most pressing calls for action. This includes supporting provider education efforts through CDC, working with provider organizations and external groups.
- In November of last year HHS released the Health+ Long COVID Report to better understand the complexities of Long COVID and cultivate creative patient-driven solutions. The Health+ Long COVID Report was commissioned by HHS and produced by an independent third-party design and research firm and includes opportunity areas where clinicians, patient advocacy organizations, public health professionals and leaders in government can improve accessibility to support and services through practical solutions.
- HHS is also working to investigate and promote evidence-based care models. For example, we are investigating how health care systems can utilize telehealth to reach patients in rural communities; how telementoring can connect expert clinicians to primary care practices; and how we advance the development of multispecialty clinics to provide complex care.
- This work would fund institutions across the country that bring together leading researchers and care providers across the full care continuum – including hospitals, health centers, long-term care services and supports, and other providers – and promote the implementation of new evidence into care, especially for disproportionately affected populations.

Q: We are now in the 4th year of the pandemic, why don't we know more about Long COVID already?

- Research is rapidly emerging and every week the scientific and medical community around the world is getting a better understanding of the various Long COVID endotypes and the differing pathophysiology; distinctions necessary to develop diagnostics and therapeutics.
- Long COVID is not one entity, so dissecting it into understandable and manageable components will take time.
- Research is establishing clinical criteria for diagnoses and elucidating possible pathophysiologic mechanisms to inform laboratory and other test development and other diagnostic strategies.
- This foundational research is already providing valuable insights and will inform Long COVID clinical trials, which will help find treatments for those suffering from its effects.
- The U.S. government has a leading role in this Long COVID research through the work it conducts itself, including research in government-led health systems such as the VA and Indian Health Service; by funding private research; and by coordinating efforts across public and private entities.
- The National Research Action Plan lays out the higher level approach to getting this work done.

Q: It seems like HHS is blowing Long COVID out of proportion to scare people-I understand that data from CDC shows that Long COVID is not real.

- Research suggests between 5% to 30% of those who had COVID-19 struggle with Long COVID symptoms 30 days after their acute infection.
- On December 1, in JAMA Network Open, an academic group of CDC INSPIRE grantees published an interim analysis of overall well-being 3 months after a positive test for SARS-CoV-

2 among an initial adult cohort of 1000 (of the estimated final cohort of 6000) in an multicenter prospective longitudinal cohort study.

- After statistical adjustment, comparing baseline and overall self-reported well-being at 3 months, improvements were greater in the COVID-19 group vs the negative group for social participation, especially among those aged 18 to 34 years and those presenting to ambulatory care for testing. Changes in other domains were not significant.
- The results of the study are preliminary, introduce the INSPIRE study, and demonstrate the importance of a control group. The findings highlight the potential widespread impact of the pandemic on our overall health, including the lesser-tracked emotional, social, and mental aspects, alongside the highly recognized physical effects.
- It is important we recognize that these findings do not negate the existence of Long COVID, or call into question the reality of the patient experience. Infection associated chronic illness is not new. There is substantial ongoing research on infection-associated chronic conditions and other diseases that may have infectious origins, including dysautonomia and ME/CFS. It is important to build on this research to achieve a deeper understanding of Long COVID and guide us to effective responses that protect the nation's long-term health.

Q. I continue to read in the news that people with Long COVID are being denied Social Security Disability Insurance. What is HHS doing to ensure SSA is working to provide economic relief for those who have become disabled or unemployed due to Long COVID?

- I defer to my colleagues at the Social Security Administration to provide more information on Social Security Disability Insurance (SSDI). However, we are working with them closely to move forward.
- I do want to share that separate from SSDI, HHS worked with the Department of Justice to publish guidance on Long COVID as a disability. Long COVID may be considered a disability under civil rights laws, which can protect people from discrimination.
 - o Titles II (state and local government) and III (public accommodations) of the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973 (Section 504), and Section 1557 of the Patient Protection and Affordable Care Act (Section 1557). Each of these federal laws protects people with disabilities from discrimination.

COVID – Mandates

TALKING POINTS:

- Time and time again, we have seen that the vaccine is both incredibly safe and effective against severe disease and death from COVID-19.
- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.
- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - o 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.

If asked about foreign national mandate:

- Evidence continues to show that vaccination does offer substantial protection against severe infection and hospitalization, and vaccines do offer some protection against infection.
- Having fully vaccinated travelers reduces the impact on the US public health and health care system.
- That said, the Administration is engaged in ongoing discussions about this policy.

QUESTIONS:

Q: Why is there still a Vaccine Mandate in place for health care workers when the PHE is ending May 11th?

- One way to prevent health care workforce shortages is to ensure they are healthy.
- The staff vaccination requirement for all Medicare and Medicaid certified providers has been enforced in all states since February 20, 2022. To date, most providers surveyed by states have been found to be in substantial compliance with this requirement.
- The requirements in the Omnibus COVID-19 Health Care Staff Vaccination interim final rule with comment will expire on November 5, 2024 if CMS does not take additional action.
- That said, the Administration is engaged in ongoing discussions about this policy.

Q: Why is there still a Vaccine Mandate for Head Start when there is a shortage of child care access for working families?

- One way to prevent health care workforce shortages is to ensure they are healthy.

- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.
- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.
- That said, the Administration is engaged in ongoing discussions about this policy.

Q: Why did CDC close schools?

- This Administration prioritized opening schools for the critical role they play in not only educations, but support for children through school meal programs and social, physical, behavioral, and mental health services.
- Three weeks after this Administration took office, CDC released guidance that served as a roadmap for how schools could open safely.
 - Prior to the release of this guidance only 46 percent of schools were offering full-time instruction. Just a few short months after, over 60 percent of schools offered full-time instruction and by the fall of that year, 95 percent of schools offered full-time instruction.

Q: Why did CDC send its school guidance to the teacher's union?

- When developing guidance and recommendations, CDC often engages with organizations and groups that are impacted. The agency does so to ensure recommendations are comprehensive, consider stakeholder needs and concerns, and are feasible to implement.
- These informative interactions result in beneficial feedback for final revisions to promote clarity, completeness, and usability.
- For the development of the school guidance, CDC had close engagement with the U.S. Department of Education and sought input from 50+ different organizations and stakeholders—including teachers, superintendents and parents to discuss experiences, challenges, and lessons learned in implementing prevention strategies for infectious diseases in K-12 schools.

Q: What is CDC's role in setting vaccine mandates?

- CDC collects data on the effectiveness of vaccines and the uptake of those vaccines in population groups (general public, healthcare workers, children, etc)
- CDC also provides information to the general public and policymakers about the state of infectious disease outbreaks (influenza, COVID-19, mpox)
- CDC makes recommendations about who should be vaccinated and when based on the science

- CDC makes this information available to policymakers who are ultimately responsible for making decisions about vaccine requirements. Policymakers can use this information to make decisions about the populations they are responsible for protecting.

Q: Now that we know the vaccines do not prevent transmission, will you go on the record to acknowledge that there is no scientific rationale justifying a vaccine mandate for COVID-19?

- The data continues to show that vaccines are very effective at reducing severe disease and death and that vaccination is the safest way to protect yourself and loved ones from COVID-19.
- In November 2022, people ages 5 years and older and vaccinated with an updated (bivalent) booster had:
 - 12.7 times lower risk of dying from COVID-19 compared to unvaccinated people.
- That said, the Administration is engaged in ongoing discussions about these policies.

COVID - Misinformation

TALKING POINTS:

- Bridging the health equity divide has been a critical component of the COVID-19 pandemic response. Americans in rural, urban, and tribal areas must have access to public health interventions and we are actively finding and closing these gaps.
- HHS is working to reach people where they are, but disinformation and misinformation often reaches them faster.
- We needed trusted messengers to help. Americans don't always want to hear from a government official, sometimes they want to hear from somebody in their local pharmacy or their local pediatrician.
- HHS works with our Pharmacy Partners and our We Can Do This campaign to use trusted community messengers to answer questions and provide accessible information about vaccines.
- It takes all of us to tackle disinformation and misinformation.

Questions:

Q: What is the impact of misinformation regarding vaccines?

- Vaccination coverage has dropped a total of 2 percentage points since the start of the pandemic for kindergartners. In real terms, this **means 250,000 kindergartners not getting their vaccinations.**
- To stop misinformation from eroding public trust in vaccines, CDC will continue its work with local partners and trusted messengers to improve [confidence in vaccines](#) among groups placed at higher risk, including racial and ethnic minorities and with parents of very young infants and expectant parents.

Q: While serving in this Administration, have you, or any of your staff, ever asked a technology company to take down an American's social media post regarding the pandemic response?

- Thank you for the question. Because there is pending litigation, I'm not going to get into any specifics on that today. But what I will say is that COVID-19 misinformation spread online is a serious issue that has real public health impacts.

Q: What is HHS doing to combat misinformation?

- HHS has undertaken a campaign which has activated partnerships, digital outreach, influencers, and paid media to reach Americans where they are, with a focus on outreach around new COVID-19 vaccine authorizations.
- The campaign has hosted over 400 COVID-19 vaccine educational booths and vaccine pop-up clinics in more than 90 cities. HHS has also launched the COVID-19 community corps, a network of nearly 20,000 community leaders and volunteers who serve as trusted local voices.

COVID – Origins

COVID – Origins (China)

TALKING POINTS:

- For more than two years, China has blocked international investigators and members of the global public health community from accessing information related to COVID-19 origins. This is unacceptable – and we must not let this prevent us from getting answers.
- The fact is that the Chinese government hasn't been transparent enough. For us to be able to get to the bottom of this, we need critical information about the origins of this pandemic that exists in the People's Republic of China.
- Yet from the beginning, government officials in China have worked to prevent international investigators and members of the global public health community from accessing it.

QUESTIONS:

Q: Will this Administration hold China accountable for obstructing efforts to investigate covid origins?

- The fact is that the Chinese government hasn't been transparent enough. This is unacceptable – and we must not let this prevent us from getting answers.
- We will continue to work with partners around the world to press China to fully share information and to cooperate with international investigations.
- Getting to the bottom of the origins of COVID-19 remains a priority for this Administration.

Q: Do you support calls to sanction China until it fully complies with international investigations?

- I'm not here today to opine on foreign policy. But what I will say is that the Chinese government hasn't been transparent enough on this issue – and that is unacceptable.

COVID – Origins (IC Assessments)

TALKING POINTS:

- President Biden has directed, repeatedly, every element of our intelligence community to put the effort and resources behind getting to the bottom of the origins of COVID-19.
- There are a variety of views on this issue in the intelligence community. Some elements have reached conclusions with varying levels of confidence on one side, some on the other, and others have said they don't have enough information.
- Valuable, bipartisan work remains to be done to address the Chinese government's lack of transparency and ensure investigators can access this critical information about the origin of COVID-19, so we can better understand how to prevent future pandemics.

QUESTIONS:

Q: Do you think that the “lab leak” theory is misinformation or a conspiracy theory?

- I think it's important to be precise here. On the one hand, some elements of the intelligence community have concluded, with varying degrees of confidence, that the coronavirus may have escaped from a lab. However, I am not aware of any evidence that the coronavirus was intentionally released as a biological weapon.
- There is no doubt that this is an important question. That's why this Administration has, from the beginning, prioritized efforts to get to the bottom of the origins of COVID-19.

Q: Both the Energy Department and the FBI have now concluded that the coronavirus likely originated from a lab leak. What is HHS's current assessment?

- We don't currently know the precise origins of the pandemic.
- The scientific evidence to date suggests that the virus is the result of normal viral evolution and not the result of genetic modification in a lab.
- The question that remains is if researchers working with infected bats or samples accidentally became infected and unintentionally spread it to others.
- There is no hard evidence to indicate that this happened, but certainly, it's something we want to know. Importantly, that will require cooperation from China and other countries to get to that information.

Q: Did Dr. Fauci tell the truth about Covid origins?

- Political attacks on public health officials like Dr. Fauci who have spent their careers saving lives are completely counterproductive.
- Dr. Fauci has said he agrees with the President that we need to get to the bottom of how COVID originated.
- I'll let Dr. Fauci speak for himself. We have been grateful for his wisdom and advice during the COVID response, and we have all been very clear that we will use every tool to figure out what happened here.

COVID – Origins (EcoHealth/Gain of Function Research)

TALKING POINTS:

- Research on infectious diseases helps develop vaccines and treatments and needs to be done safely, securely, and transparently -- here and abroad.
- HHS takes its responsibility to be a good steward of taxpayers' investment in biomedical research seriously.
- To that end, last year HHS tasked the National Science Advisory Board for Biosecurity (NSABB) to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.

- The NSABB issued its final report and recommendations earlier this month. HHS, and our interagency partners, will consider this report as part of a broader government-wide review process, which aims to effectively balance science and security, while safely enabling critical lifesaving research.

QUESTIONS:

Q: Did the NIH through its EcoHealth grant fund gain-of-function research in the Wuhan Institute of Virology (WIV) that resulted in COVID-19?

- No. NIH has never approved any research that would make a coronavirus more dangerous to humans.
- The research we supported in China, where coronaviruses are prevalent, sought to understand the behavior of coronaviruses circulating in bats that have the potential to cause widespread disease.
- The body of science reported—including the bat coronavirus sequences published in the scientific literature—showed that the viruses studied at WIV under the NIH grant were evolutionarily quite distant from SARS-CoV-2 and could not have been the source of the COVID-19 pandemic.
- And importantly, because of similar research to understand coronaviruses, we were able to move swiftly to develop vaccines against SARS-CoV-2 and save lives.

Q: Why does HHS support research in China at all?

- HHS supports research to better understand the characteristics of animal viruses that have the potential to spill over to humans and cause widespread disease.
- We must collaborate with researchers in other countries where these sorts of viruses are prevalent because once a virus spreads to humans, it is not contained by geographical boundaries.
- Infectious outbreaks have happened throughout history. Let's not forget the SARS epidemic in 2003 that was traced to civets as an intermediate host or the H1N1 flu pandemic in 2009 that originated from pigs.
- The body of research on pathogens and infectious diseases is what has made it possible for the U.S. government to move so quickly to get a COVID-19 vaccine in an unprecedented timeframe of just 11 months. Countless lives have been saved as a result.

Q: What is this Administration doing to ensure taxpayers are not funding risky biomedical research that could lead to another public health crisis?

- In February 2022, NIH tasked the National Science Advisory Board for Biosecurity (NSABB) to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.
- In March 2023, the NSABB issued its final report containing its findings and recommendations.

- These findings and recommendations will inform ongoing USG policy deliberations.

Q: The HHS OIG recently found that NIH did not effectively monitor or address EcoHealth's compliance with grant requirements, when it was conducting risky research at the WIV. Dr. Larry Gostin, who has advised this White House on the pandemic response, called the OIG report a "damning indictment of NIH." Do you agree?

- We respect the OIG's findings and have taken action to address their recommendations.
- HHS takes its responsibility to be a good steward of taxpayers' investment in biomedical research seriously. We are committed to conducting oversight of the research we fund to ensure safety, security, and responsible conduct.
- That's why we charged the NSABB to review existing policies and provide recommendations that seek to ensure U.S. biosecurity efforts are positioned to keep pace with an evolving scientific enterprise.
- Additionally, recipients of NIH awards are accountable for ensuring the stewardship of federal funds and must comply with all applicable federal statutes, regulations, policies, and institutional requirements.

COVID - OTC Tests

TALKING POINTS - MEDICARE:

- CMS prioritizes supporting beneficiary access to the care they need and after the end of the public health emergency (PHE).
- Medicare beneficiaries can continue to access medically necessary COVID-19 polymerase chain reaction (PCR) tests and antigen tests performed by a laboratory at no cost to them when the test is ordered by a physician or non-physician practitioner and some Medicare Advantage plans may continue to provide coverage for these tests as a supplemental benefit.
- By law, Medicare does not generally cover over-the-counter (OTC) services and tests. Current access to free OTC COVID-19 tests will conclude at the end of the PHE. When the demonstration was implemented, it was announced that the demonstration would end at the end of the PHE.

TALKING POINTS – OTHER PLANS:

- The requirement to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end at the end of the PHE - coverage may continue if plans choose to continue to include it, which we are encouraging them to do.

QUESTIONS:

Q: Will CMS be extending the Medicare OTC demonstration?

- When CMS implemented this demonstration, we stated that CMS would pay claims for over-the-counter COVID-19 tests starting on or after April 4, 2022, through the last day of the COVID-19 public health emergency, which the President announced would be May 11, 2023.
- After the end of the COVID-19 PHE, Medicare beneficiaries can continue to access medically necessary COVID-19 polymerase chain reaction (PCR) tests and antigen tests performed by a laboratory at no cost to them when the test is ordered by a physician or non-physician practitioner.
- Some Medicare Advantage plans may cover and pay for at-home over-the-counter COVID-19 tests as a supplemental benefit in addition to Medicare Part A and B benefits, so consumers enrolled in Medicare Advantage plans should check with their plans to see if they offer this benefit separate from coverage for all Part B enrollees under the demonstration.

Q: What about Medicaid coverage?

- Under the American Rescue Plan Act of 2021, State Medicaid programs are required to cover FDA-authorized home diagnostic and screening tests for COVID-19 for most

Medicaid beneficiaries without cost-sharing, until the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE.

- Because Medicaid coverage parameters may vary by state, people dually eligible for Medicare and Medicaid and who are eligible for full Medicaid benefits should contact their state Medicaid agency for information regarding the specifics of Medicaid coverage for at-home COVID-19 tests.

Q: What about private insurance coverage?

- The requirement for group health plans and health insurance issuers offering group or individual health insurance coverage to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end at the end of the PHE. However, coverage may continue if plans choose to continue to include it. We are encouraging private insurers to continue to provide such coverage going forward.

COVID - Vaccine Safety

TALKING POINTS:

- Time and time again, we have seen that the COVID-19 vaccines are both incredibly safe and effective against severe disease and death from COVID-19.
- Vaccination remains the safest and most dependable strategy to build immunity. Most adverse events following vaccination are mild and resolve quickly, such as pain at the injection site and fever. Serious adverse events are rare.
- That said, COVID-19 vaccine safety remains a top priority for HHS, and reports of health problems are taken seriously. CDC, FDA and its partners use several complementary vaccine safety systems to monitor for adverse events.
- We are dedicated to transparency and report findings from safety monitoring publicly, as part of an open and transparent process, to CDC's Advisory Committee on Immunization Practices (ACIP), to FDA's Vaccines and Related Biological Products Advisory Committee, and to update the information for health care providers, caregivers and recipients, as appropriate

QUESTIONS:

Q: HHS agencies have repeatedly told the American people that the vaccines are safe. But CDC's data monitoring system has detected evidence of a link between the vaccines and strokes. Can you acknowledge that your Department's own data show that the vaccines pose risk of serious adverse effects for at least some Americans?

- For decades, our scientific agencies have used safety monitoring systems to look for even the slightest clue of a potential safety issue in our medicines, including vaccines. In most cases, signals detected by these systems do not add up to safety risks, but we investigate all these signals to ensure trust in our medicines.
- As part of CDC's routine surveillance, CDC detected a signal for potential stroke in people ages 65 and older who received the Pfizer-BioNTech bivalent vaccine. In response, CDC and FDA examined several large databases to see if these systems had detected a similar signal. To date, our analyses of all of these large databases do not show an association or increased risk of stroke from the Pfizer-BioNTech bivalent vaccine.
- We continue to conclude that the bivalent vaccines are safe and effective and provide the best protection against COVID-19, and we continue to recommend that Americans of all ages get their updated COVID-19 vaccine right away.

Q: Americans have been pressed to take a series of vaccine doses in less than two years. And now, this Administration is indicating that the public—including children—should

expect a sustained pressure campaign to take a shot each year. If the vaccine is so effective, how come Americans are being asked to take them constantly?

- Evidence continues to show that the COVID-19 vaccine is remarkably safe and effective at preventing severe disease and death.
- Vaccination also does reduce the impact on the US public health and health care system.
- And making sure you are up-to-date on booster shots is an important part of protecting yourself from getting seriously ill or dying from COVID-19.

Cybersecurity

TALKING POINTS:

- Cyber incidents pose risks to patient data, intellectual property, scientific research, medical manufacturing, and ultimately the ability of health care organizations to safely serve their patients. We must take all steps necessary to prevent them.
- Just this month, the Department released a new roadmap to help health care organizations improve their cybersecurity amid new emerging threats and increased attacks on systems. We hope to leverage and further incentivize our private sector partners to strengthen critical infrastructure and safety writ large.
- In February, we announced that our Office for Civil Rights is realigning to address this spike in health data breaches. Across the board, we are working to remain nimble internally to respond to bad actors throughout the sector.
- In December, the FDA received new authorities through the omnibus requiring medical device manufacturers to implement cybersecurity protections on devices before they hit the market.

QUESTIONS:

Q: How concerned are you about cyber attacks in the healthcare sector? How is HHS helping when cyber incidents occur?

Patient safety is our #1 priority, and safety is compromised by these cyber incidents. A significant consequence of US hospital-directed cyberattacks are the extended disruptions that are caused by long outages and disrupt our healthcare system's ability to provide care (e.g., strain on acute care capacity and ability, causing loss of appointments, loss of services, and delayed medical procedures).

These attacks also cost hospitals financially – one recent attack on a major health system cost them at least \$150M; the \$150 million financial impact includes lost revenues due to business disruption and extra costs to fix the IT issues. These attacks threaten the solvency of health care facilities, and thus can potentially reduce access and availability of care.

When incidents occur, we work with our government partners, such as CISA and FBI to investigate; HHS investigations center around the impact to patient safety.

We stand ready to protect patients when incidents occur through our incident response capabilities within ASPR.

Q: What is HHS doing to support the healthcare and public health sector on cybersecurity?

The best defense is a good offense – we encourage providers to be proactive and take the necessary steps to prevent incidents by securing their networks and data.

HHS partners with our private sector and interagency partners to release cybersecurity guidance and best practices for health care organizations to implement; we encourage healthcare organizations to remain vigilant.

Additionally, any data breach with patient data is reported to the Office for Civil Rights for further investigation – and follow on action (including penalties) as necessary. Finally, the FDA plays a big role through the regulation of medical devices – through the FY 2023 omnibus the FDA will now have the authority to require cybersecurity protections on medical devices BEFORE they enter the market.

DEA Regulations

TALKING POINTS (TELEMEDICINE)

- DEA released new **proposed** regulations related to the practice of telemedicine.
- HHS has worked with our DOJ partners on these proposed rules to make sure that people can continue to access telemedicine for critical controlled medications, including buprenorphine treatment for Opioid use disorder.
- Finalizing regulations to extend these flexibilities is critical to ensure minimal disruption and a smooth unwind of the public health emergency
- At HHS, our priority is ensuring access to care for critical services. Pre-pandemic law would be a dramatic rollback of what we learned to be critical access to care that can often be lifesaving.
- We look forward to stakeholder feedback and working with our DOJ colleagues to take that into account and finalize a rule.

TALKING POINTS (X-WAIVER):

- The Omnibus included provisions that better integrate opioid use disorder care into primary care and expand access in rural areas, which the DEA and SAMHSA are implementing. This includes:
 - Removal of the X-waiver and removal of buprenorphine patient caps
 - Implementation of one-time training and education requirements for prescribers wishing to prescribe medication assisted treatment (MAT)
- We are currently working across the Administration to implement these new provisions related to substance use disorders and to produce informative materials for those who are impacted by the new provisions.
- We are supportive of efforts to reduce barriers to treatment because ultimately, this is about saving lives.

QUESTIONS – TELEMEDICINE:

Q: What happens on May 11 when the PHE expires?

- Our work with DEA is about making permanent changes to the regulations that currently apply from pre-pandemic days.
- Once the PHE expires on May 11, and state-level PHE's expire, we know we should not go back to operating the way we did pre-pandemic. We have learned how lifesaving telemedicine is and want to permanently put into place what we know is critical to improving access to healthcare.

- This is why it's critical to take these steps as soon as possible and permanently put in place new, more expansive flexibilities (*as compared to pre-pandemic*) before the PHE expires on May 11.
- We know this is a complicated issue, and we want to make sure we get it right, which is why robust comment is so important during this comment period.

Q: You are encouraging the public to comment but didn't the announcement come out after 7pm on a Friday evening?

- We are in a time limited situation, and we want to get it right. We announced this as soon as we got it cleared because every day counts.
- We need to hear from the public on this rule so we can get this right.
- If these updated, more flexible regulations do not go into place as soon as the PHE expires, we will be left with the older pre-pandemic policies governing telehealth initiation of controlled medications, which were far more restrictive – and everything we learned about improving access to care will be lost.

Q. You claim to support access to buprenorphine, yet the DEA's proposed rules would roll back some flexibilities that have been in place since the pandemic started. Do you support this proposal?

- We have heard lots of differing perspectives on the proposed rules and appreciate the stakeholder engagement.
- We are in a time limited situation, and we want to get this right. Going back to Pre-pandemic rules would dramatically rollback access.

QUESTIONS – X-WAIVER:

Q: How will the removal of the X-Waiver improve access for patients to medications for opioid use disorder?

- The removal of the requirement for practitioners to obtain a waiver will make it easier for qualified practitioners to prescribe medications for opioid use disorder, builds on the Department of Health and Human Services' Overdose Prevention Strategy, and delivers on the call to action in President Biden's Unity Agenda to expand access to evidence-based prevention, treatment, and recovery services.

Q: Isn't removing the training requirement in the X-waiver a concern? Isn't that how we got in this epidemic in the first place?

- The alarming increase in overdose deaths underscores the need for more accessible treatment services, and studies have shown that medication-based treatment promotes long-term recovery from opioid use disorder.

- The spike we've seen in opioid involved deaths during the COVID-19 pandemic requires us to do all we can to make treatment more accessible.
- At the same time, we know that education on substance use disorders is important as practitioners diagnose and treat these conditions. HHS is working with professional societies to ensure that appropriate education is provided to their members so that the ongoing education and training needs of healthcare professionals are met, regardless of the existence of the X-waiver itself.

Q: Is there abuse potential for buprenorphine-naloxone? In other words, could someone use it to achieve a "high?"

- Though we are aware of some diversion of buprenorphine, these instances are rare and when they do happen, it is typically because people are seeking treatment, not attempting to get "high." This is all the more reason for us to take steps to expand access to buprenorphine.

Q: Will HHS maintain the regulatory flexibilities for medication-assisted treatment for the remainder of the Public Health Emergency while it considers making these policies permanent?

HHS, through SAMHSA, has indicated it will work to revise the relevant regulations to make permanent some flexibilities for opioid treatment programs.

Debt Ceiling

TALKING POINTS:

- The Administration's position has been clear – we must avoid dangerous brinksmanship and agree to a clean raise of the debt ceiling.
- The President's budget will build on the last few years' progress, invest in America, and strengthen our fiscal outlook.
- The Administration welcomes a conversation with congressional Republicans about their competing vision, and that's why we've urged them to put forward their own budget, which is a necessary step to having that conversation.
- The President has been clear about some things he won't agree to, including cutting Medicare benefits or taking away people's health care.

QUESTIONS:

Q: Will this Administration accept work requirements for Medicaid beneficiaries?

- Let's be clear: Medicaid is a lifeline to tens of millions of hardworking American families across the country.
- My goal is to use all available tools to protect and strengthen the Medicaid program, making it easier, not harder for people to get and keep health insurance that helps them to become healthy, not pulls the rug out from under them.
- *If pushed:*
We would not approve any demonstration that would result in significant numbers of Medicaid beneficiaries losing coverage.

Q: Will this Administration negotiate on Medicaid

- Medicaid is a lifeline to tens of millions of hardworking American Families- including one in every two children. The President's budget would strengthen our fiscal outlook and cut the deficit by investing in America, not paying for it on the backs of hardworking families.

Q: What will cuts to non-defense discretionary spending mean for HHS?

- This is the funding for medical research, public health programs at the CDC and other HHS agencies, grants for substance use and mental health treatment, and various other programs.
- Cuts will have a significant impact on the Department's work and ability to provide services, assist people in need, and make necessary investments.

(CMS) Drug Pricing Reform

TALKING POINTS:

- The Budget builds on the transformative prescription drug provisions included in the Inflation Reduction Act to further lower the cost of prescription drugs for Americans:
 - Strengthen Medicare's newly established drug pricing negotiation power by allowing Medicare to negotiate prices for more drugs and bringing drugs into negotiation sooner after they launch, saving \$160 billion over 10 years.
 - Extend the requirement that drug companies pay rebates when they increase prices faster than inflation to commercial health insurance, not just Medicare.
 - Limit cost-sharing for insulin to \$35 per month for all consumers covered by commercial plans, not just Medicare beneficiaries.
- The Budget further reduces out-of-pocket costs for people with Medicare by capping copayments for Part D generic drugs at maximum of \$2 per prescription per month.
- The Budget addresses the high cost of drugs in Medicaid and CHIP by establishing a process for CMS to lead states in negotiating supplemental rebates to pool purchasing power for lower prices.

QUESTIONS:

Q: How many drugs are you including in your proposal to expand drug price negotiation to achieve \$160 billion in savings over 10 years? Is that realistic?

A: First, let me say that I am proud to be part of the Administration that passed one of the most significant health reform bills since the creation of Medicare. The Inflation Reduction Act makes Medicare stronger for current and future enrollees. It makes health care more accessible, equitable, and affordable by lowering what Medicare spends for prescription drugs and limiting increases in prices, reducing the deficit by \$159 billion.

Our Budget builds on the Inflation Reduction Act by increasing the number of drugs subject to negotiation, eventually negotiating on up to 40 drugs, and making drugs eligible for negotiation sooner after their launch. Expanding the Drug Price Negotiation Program will lower costs for people with Medicare and the program, for an additional \$160 billion in savings over 10 years.

We will take the increased savings and put them directly into the Medicare trust fund, helping to extend Medicare's solvency. As always, we will continue to work with Congress on the specifics of these proposals.

Q: Won't drug price negotiation raise the prices of new drugs, so doesn't the Budget contribute to higher prices for new drugs?

A: Manufacturers use many factors when considering their launch prices and will continue to price their drugs at the price they believe the market will bear. We are proposing to make drugs eligible for negotiation sooner after they launch, permitting time on the market for five years. Under current law and under our proposal, any drug or biological product selected for

negotiation will have been on the market for some time. CBO didn't estimate that the new Drug Price Negotiation program would have a significant impact on launch prices, and we do not believe our proposal will contribute to significantly higher launch prices.

Q: Aren't drug price negotiations really price controls that will hinder drug development?

A: We support innovation and believe it is vitally important that people with Medicare have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.

By reducing prices for high-cost drugs, our expansion of Medicare drug price negotiation will not only save money for the federal government, but it will also cut Medicare beneficiary out-of-pocket costs by billions of dollars.

Q: Won't drug price negotiation crush innovation and kill hundreds of new cures? Studies have found that the IRA's negotiation provision would kill up to 342 cures.*

A: We support innovation and believe it is vitally important that people with Medicare have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.

Medicare's drug price negotiation program will make drugs more affordable for people with Medicare. Remember, only drugs that have been approved or licensed by the FDA for a number of years are eligible for negotiation.

*[The number 342 has been used by some to argue that drug price negotiation will lead to fewer new drugs and refers to a [University of Chicago study](#) based on provisions in H.R.3, Lower Drug Costs Now, that finds fewer drug approvals ranging from 167 to 342.]

Q: Regarding making the Medicaid Drug Rebate Program (MDRP) optional for territories, why is this needed? Doesn't joining the MDRP result in more savings for territories?

A: Territories' Medicaid programs operate under a unique set of conditions that differ from states. While participating in the Medicaid Drug Rebate Program leads to savings, these savings could be more than offset by the increase in costs from the additional drugs that territories would need to cover under the MDRP. The five territories are very different and will not experience the same economic impact by joining as states. This proposal effectively gives territories the option to make the best choice for their Medicaid program resources and needs. Excluding sales of drugs to territories from the average manufacturer price and best price calculations mitigates possible increased drug prices in territories.

Drug Pricing Executive Order

TALKING POINTS:

- HHS was tasked by the President to select models to test to bring down prescription drug costs.
- I selected three models identified by the Innovation Center that we believe will lower prescription drug costs and improve access for people with Medicare and Medicaid, including, in Medicare, access to certain generic drugs for no more than \$2.
- To help identify model options, we solicited input from a variety of sources including beneficiary advocates, health care providers, and prescription drug manufacturers, and we look forward to additional input as these models are further developed.

If pressed about mandatory models

- Two of the models are voluntary. Only one model, the Accelerating Clinical Evidence Model, would be mandatory for physicians billing Medicare for Part B drugs, and this model would only be implemented after a full notice and comment rulemaking cycle.

QUESTIONS:

Q: The FDA's Accelerated Approval Program has brought groundbreaking therapies to patients' years before these products would have otherwise reached the market. The Accelerating Clinical Evidence Model recently announced by CMS risks undermining this progress. Will you consider canceling or delaying the Model?

- The Accelerating Clinical Evidence Model will not change the way CMS covers new drugs, and it does not change the FDA accelerated approval process. The model is intended to test whether changes to Medicare payment might encourage evidence development via timely completion of confirmatory trials. We are still exploring the specific approaches to payment adjustments, and we look forward to close consultation with the FDA and hearing from stakeholders on how the Model should be developed.

Q: The IRA did not address the high cost of drug launch prices; how will these models tackle that challenge?

- High launch prices are among many factors that impact affordability for beneficiaries. Each of the selected models addresses the objectives of the President's executive order and meets the selection criteria of increasing affordability, accessibility, and feasibility of implementation.

Q: The IRA did not address the perverse incentives created by PBM rebates, how will these models tackle that challenge?

- The executive order directed the Innovation Center to explore a variety of factors addressing prescription drug costs. The effect of rebates on prescription drug costs is one among many factors that contribute to high and rising drug costs for beneficiaries. The selected models address the objectives of the President's executive order and meet the selection criteria of increasing affordability, accessibility, and feasibility of implementation.

Q: Part D plans already offer low-cost generics; what does the High-Value Drug List model intend to accomplish?

- This model would encourage plans to expand their current low copay drug offerings and provide beneficiaries access to a standardized list of generics with copays of no more than \$2 across participating plans. The simplicity and consistency of the drug list could provide beneficiaries with greater predictability and transparency with their drug costs and enable them to more easily access low-cost generics.

Q: How does the Medicaid Cell & Gene Therapy Access Model differ from what states can already do?

- State Medicaid agencies may negotiate with manufacturers for supplemental rebates on prescription drugs and may form multi-state purchasing pools for purposes of these negotiations. However, states' abilities vary, and the resources necessary to negotiate outcomes-based supplemental rebate agreements are far greater than other types of rebate agreements. This model will help to address that challenge for states and encourage adoption of outcomes-based agreements on a broader scale for certain cell and gene therapies, like for sickle cell disease and cancer.

Early Childhood Education

(Dollars in Millions)

Discretionary Table	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Child Care and Development Block Grant (Discretionary)	8,021	9,000	+979
Head Start (Discretionary)	11,997	13,112	+1,115
Preschool Development Grants (Discretionary)	315	360	+45
Total, Discretionary	20,333	22,472	+2,139

Mandatory Table	FY 2023 Enacted	FY 2024		10 Years
		Budget	+/- FY 2023 Enacted	
Budget Authority - Child Care Entitlement	3,550	3,550	-	35,500
Total, Child Care Entitlement	3,550	3,550	-	35,500
Budget Authority - Affordable Child Care for American Families	-	9,900	-	400,000
Budget Authority - Universal Preschool	-	5,000	-	200,000
Total, Early Care and Education	-	14,900	-	600,000

Talking Points:

- The budget provides \$22.5 billion in discretionary Child Care, Head Start, and Preschool Development Grants, an increase of \$2.1 billion over FY 2023 Enacted. The budget also continues to help over 2.5 million children have access to early learning programs through our existing Child Care, Head Start, and Preschool Development Grants programs.
- The FY 2024 President's Budget builds on the existing Child Care and Development Block Grant by addressing its current limitations and ensuring more families can benefit, parents have more high-quality options, and providers are paid higher wages.

The President's FY 2024 Budget invests \$600 billion in affordable, high-quality child care to an additional 16 million children, and universal preschool to approximately four million 4-year old children.

QUESTIONS:

Q: How will Early Childhood Education help low and middle-income families access high quality and affordable child care?

- The President's Budget includes \$600 billion over 10 years to expand access to affordable, high-quality child care and free, high-quality preschool, helping children learn, giving families support, and growing the economy.
- Low- and middle-income families will pay the lowest co-pays – with a goal of ensuring that the lowest income families pay nothing and that most families pay no more than \$10 perday per child.
- A median-income family with young children saves about \$400 per month while accessing higher quality care.

Q: What is in the Early Childhood Education - Affordable Child Care for American Families proposal?

- The FY 2024 Affordable Child Care for American Families proposal costs \$400 billion over 10 years and ensures low-income families pay nothing and that most families pay no more than \$10 perday per child.
- This FY 2024 proposal includes a sliding scale where families making less than \$30,000 will pay nothing while those earning up to \$200,000 will pay \$30 perday perchild.
- The FY 2024 proposal includes a 20 percent state match to serve families earning above \$30,000 and a 40 percent state match for families earning above \$100,000.

Q: What is in the Early Childhood Education - Universal Preschool proposal?

- The Universal Preschool proposal expands high-quality preschool to approximately four million 4-year-old children, with states later expanding to 3-year-old children once preschool is expanded to all 4-year-old children.
- The Universal Preschool proposal includes \$20 billion in capped funding with no state match for the firstthree years, to enable states to build capacity of preschool programs and start expanding preschool to children in underserved communities.
- The Universal Preschool also includes \$30 billion to serve children in non-participating states through Head Start and
- local governments in underserved communities.

Equity

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
ACF	71,470	94,374	+22,904
ACL	2,105	2,551	+445
AHRQ	4	12	+9
CDC	378	674	+297
FDA ¹	19	19	--
HRSA	7,589	8,634	+1,045
IHS ²	7,105	9,650	+2,545
NIH	95	95	--
CMS	83	82	-1
OASH	75	86	+11
OCR	40	78	+38
Total Program Level	88,963	116,256	26,293

1/The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year

2/ Reflects total IHS funding with the exclusion of third-party collections. The FY 2024 budget proposes mandatory funding for Contract Support Costs and Section 105(l) Leases. Funding for these activities is discretionary in FY 2023.

TALKING POINTS:

- Equity remains a core value and consideration in the Department's budget and program implementation. We strive to reduce systemic health and social disparities for individuals and families, and combat inequities in access to care.
- Some highlights in our budget – we included \$8.6 billion to care for low-income and underserved populations through Health Centers, health care workforce expansion, rural health, HIV/AIDS, and maternal and child health services. The budget takes long-overdue action to improve the health status of over 2.8 million American Indians and Alaska Natives served by the Indian Health Service (IHS) with historic funding levels. ACF also will provide \$50 million in new grants to address racial inequities in child welfare, and reduce overrepresentation of racial / ethnic minority children and families.
- The budget invests over \$2.6 billion to provide critical services and supports to older adults and people with disabilities, with a particular emphasis on serving the most vulnerable in greatest social and economic need (through Administration for Community Living (ACL) programs).

QUESTIONS:

Q: In what ways has CMS focused on equity in the budget?

There are many proposals in the budget that have a positive equity impact. Key examples include:

- **Medicaid:** The budget eliminates barriers to Pre-exposure Prophylaxis (PrEP) for HIV/AIDS, increases access for Medicaid beneficiaries seeking HIV prevention tools, including populations most vulnerable to HIV/AIDS. The budget also requires postpartum coverage for 12 months under Medicaid, including for populations with the highest maternal and infant mortality rates. It also supports dually-eligible individuals by reducing administrative barriers for enrollment and simplifying the process for renewing eligibility in the Medicare Savings Program.
- **Medicare:** The budget also improves data on health disparities by requiring post-acute care providers to report standardized data on social determinants of health, and allows the collection of demographic and social determinants data through Medicare quality reporting programs. The budget adds Medicare coverage of services furnished by community health workers to improve access for underserved beneficiaries
- **Private Insurance:** The budget would fulfill the intention of the ACA by providing a premium-free plan to individuals below 138 percent of the poverty level in states that have not expanded Medicaid, potentially decreasing the number of uninsured individuals by over 2 million. This proposal is a \$200 billion allowance government-wide.
- **Program Management:** The budget includes \$25 million in discretionary budget authority for an initiative to develop tools for States and tribes to address disparities, expand innovative approaches for integrating equity into CMS's programs and policies, build analytic systems to integrate data on underserved populations, and develop dashboards and other products to support interventions to reduce disparities.

Q: The CDC declared racism a public health emergency in 2021. What is the Department doing to improve minority health and reduce health disparities?

- The Health Resources and Services Administration improves health outcomes and achieves health equity through access to quality services, a skilled health workforce, and innovative, high-value programs. HRSA is the primary federal agency that improves access to healthcare services for people who live in underserved and rural communities across the country.
- The National Institute on Minority Health and Health Disparities will continue to expand investments in research on health disparities, fostering collaborations and partnerships to address long-standing inequities.
- NIH will continue to support the UNITE initiative, an NIH-wide effort committed to ending racial inequities across biomedical research.
- Congress provided increased funding for disparities research at NIMHD in FY23. This budget will continue to fund these efforts.

Vulnerable Children + Youth

(Dollars in Millions)

Discretionary Funding	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Runaway & Homeless Youth	146	159	+13
Child Abuse Programs	214	257	+43
Child Welfare Programs	339	431	+92
Adoption Incentives	75	75	-
Family Violence Prevention Services	261	519	+259
Total Vulnerable Populations Program Level	1,226	1,683	+457

TALKING POINTS:

- It is the Department's responsibility to protect those most vulnerable among us – and that means making robust investments in care settings and supports for children in the foster care system, investments in children and youth in at-risk situations, and investments in family violence and child abuse prevention programs.
- This Administration is delivering on that mission with its FY24 budget, which increases funding for vulnerable populations across the board. To start, this budget nearly doubles funding for Family Violence Prevention Services Programs from last year's enacted levels.
- HHS is also committed to reducing child abuse and providing families with the support they need to remain safely together to avoid the trauma that results when children are placed in out-of-home-care – that's why we asked for a \$135 million increase to continue to support child welfare.
- These issues have historically had bipartisan consensus. The Department looks forward to continuing to partner with Congress to advance a child-centered and family-centered social service infrastructure.

QUESTIONS:

Q: We just marked 5 years since the bipartisan passage of the Family First Act – can you speak to how implementation is going across the country?

The Family First Prevention Services Act (FFPSA) and its title IV-E prevention services program provides a watershed opportunity to create more equitable outcomes for

children, youth, and families before they face the tumult and devastating consequences of maltreatment and separation.

ACF estimates that 6,200 children were served by title IV-E prevention services programs in FY 2022, and, as more and more prevention programs are implemented, 672,500 children will be served annually by FY 2033

We have seen great progress around the country among jurisdictions who have developed prevention plans under Family First to expand the in-home parenting skills programs, mental health programs, and substance use prevention and treatment programs in their communities.

Q: Family members are often an important part of our child welfare system, keeping kids safe, and keeping families together. What is the Administration doing to ensure that family members caring for children have the supports they need?

When parents are unable to safely care for their own children, it is often grandparents, other family members, or kin who step forward to provide a loving home for those children, either temporarily or permanently. Research is clear that children in kinship care often experience less trauma and have better outcomes across a range of behavioral and developmental well-being measures.

While kinship caregivers provide essential care to children, they often do not receive adequate support.

The Biden-Harris Administration is committed to strengthening support for grandparents and other kin caring for children by working with states to ensure equitable access to licensure for relative foster care providers and by expanding services, resources and supports for kinship caregivers and the children in their care.

The President's FY 2024 budget includes proposals to encourage placing children with relatives or kin when they cannot remain safely at home with parents.

The President's FY 2024 budget also proposes to increase support for kinship navigator programs.

Fentanyl/Overdose Prevention

TALKING POINTS:

- Drug overdoses are a leading cause of death for Americans - more than 107,000 Americans died from a drug overdose in the 12-month period ending in August 2022.
- The overdose crisis has evolved beyond the use of prescription opioids to include increased use of illicit opioids, such as fentanyl, and in combination with other drugs like cocaine and methamphetamine. We are focused on using evidence-based strategies to save lives like using naloxone and expanding access to medications to treat opioid use disorder.
- The budget addresses the **overdose epidemic** by investing \$10.9 billion, including \$9.8 billion in discretionary funding, in programs addressing opioids and overdose-related activities across HHS. These programs support the goals of the HHS Overdose Prevention Strategy.

If pressed for specific examples:

- \$6.2 billion for SAMHSA programs, including the Substance Use Block Grant and the State Opioid Response Grant, which provide grants to states to address the overdose crisis.
- \$736 million for the CDC to expand overdose prevention programs.
- \$79 million for the FDA to implement the Overdose Prevention Framework, which supports programs to promote appropriate prescribing, expand access to naloxone, ensure access to evidence-based treatments, and increase surveillance, enforcement, and indictment of illegal products at international mail facilities.
- \$50 million for a new Community Harm Reduction and Engagement Initiative that will support distribution of naloxone, prevent overdose deaths, increase testing for HIV and viral hepatitis, and provide peer support services. This program will provide much needed services to 330,000 people.
- \$78 million for First Responder Training program and \$28 million for grants to prevent prescription drug and opioid overdose—increases for these SAMHSA programs will directly increase access to naloxone and prevent overdose deaths.
- \$28 million for Building Communities of Recovery, an increase of \$12 million, to expand peer recovery services, expanding access to shared life experiences and community knowledge from peers to program participants.

QUESTIONS:

Q: Do you think that we should schedule fentanyl and fentanyl analogues?

- It is a priority for this Administration to schedule the class of fentanyl-related substances. At the same time, we should make it easier to research Schedule I substances, and create

an off-ramp to de-schedule or lower the schedule of a fentanyl-related substance if data show it doesn't belong in Schedule I. These actions are all included in the Biden Administration's interagency agreement, which I support.

- We do know that the introduction of synthetic opioids like illicitly manufactured fentanyl has led to significant increases in overdose deaths. Of significant concern is the increasing contamination of the drug supply with fentanyl. This is leading to many individuals becoming exposed to fentanyl without even knowing or expecting it.
- Given the escalating overdose crisis and the negative impact of the COVID-19 pandemic, HHS experts came together to create a comprehensive Overdose Prevention Strategy meant to strengthen our primary prevention efforts and increase access to the full continuum of care and services for individuals with substance use disorder and their families.
- The availability of fentanyl underscores the need to expand access to quality prevention, treatment, recovery support, and harm reduction services. Ultimately, this is about saving lives.

Q: Can you talk about the importance of education on fentanyl contamination in the cases of drug overdose deaths?

- We know that the introduction of synthetic opioids like illicitly manufactured fentanyl have led to significant increases in overdose deaths. We also know that people are increasingly becoming exposed to fentanyl that has made its way into the drug supply.
- SAMHSA's First Responders-Comprehensive Addiction and Recovery Act Grants is one example of a program that works to train and provide resources to first responders and other key community members, distribute naloxone and fentanyl strips, and seek to reverse overdose deaths associated with fentanyl.
- We are proposing a \$22 million increase for this critical program.
- Other grants such as the State Opioid Response program and Comprehensive Opioid Recovery Centers (CORC) grant also support access to education, outreach, and the continuum of services people with opioid and/or stimulant use disorders need.

Food Safety

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA	1,520	1,730	+210

Talking Points:

- Today, we are in the midst of a **food revolution**—including how foods are produced, delivered, and handled.
- The budget proposes **\$1.7 billion** to invest in resources, staff, and technology that address rapid changes in human and animal food safety systems and human nutrition.
- Key investments include **protecting** in infant and toddler foods, **enhancing nutrition and food labeling**, and improving the security of the food **supply chain**. For future disruptions.

QUESTIONS:

Q: How will FDA's organizational changes improve its ability to carry out its food safety responsibilities?

- FDA is implementing a new, transformative vision for the FDA Human Foods Program, which will focus on protecting and promoting a safe, nutritious U.S. food supply that more quickly adapts to an ever-changing and evolving environment.
- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Q: Does the FY24 budget's proposed increases for Foods fund these organizational changes?

The proposed increases cover needs identified in the Foods program even before the organizational changes began. As we continue to implement our transformative vision for the Human Foods Program and identify additional needs, we will come back to Congress.

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- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Gun Violence and Community Violence

TALKING POINTS:

- Firearm injury is among the 5 leading causes of death for people aged 1–44 in the United States.
- Addressing the gaps in knowledge and identifying effective prevention strategies are needed to keep individuals, families, schools, and communities safe from firearm injury and death.
- Community violence directly or indirectly affects everyone in a community as people grieve for friends and neighbors and avoid engaging in neighborhood activities. In addition, violence creates strain on education, justice, and medical systems and weakens local business growth and prosperity, limiting community resources and preventing the achievement of other community goals.

QUESTIONS:

Q: Gun violence in the U.S. is at an all-time high, it is clearly a public health threat. Will you declare a PHE for gun violence?

- You're correct, this is a crisis—firearm injury is among the 5 leading causes of death for people aged 1–44 in the United States.
- The most important thing we can do is to continue to support prevention, education and research efforts across this country.
- We want to keep all options on the table, but we are not declaring a PHE at this time.

Harm Reduction

TALKING POINTS:

- HHS is fully committed to harm reduction as part of our comprehensive approach to address addiction and the overdose epidemic.
- More than 107,000 Americans died from a drug overdose in the 12-month period ending in August 2022. We must do everything we can to save lives.
- The Administration has a comprehensive overdose prevention strategy of primary prevention, harm reduction, treatment, and recovery support services.

QUESTIONS:

Q: Can HHS or SAMHSA grantees use any federal dollars to purchase and distribute needles?

The FY 2023 Consolidated Appropriations Act Congress carried previous appropriations language that allowed for the purchase and distribution of needles so long as both local public health or local law enforcement deem it appropriate, or the State or local health department in concert with CDC has determined that the State or local jurisdiction is not experiencing or at risk for a significant increase in hepatitis infections or a HIV outbreak due to injection use.

Q: But I thought that the FY23 Omnibus included provisions that prevented grantees/states from using federal funds for the purchasing or distribution of drug paraphernalia?

- The Administration is focused on a comprehensive strategy, including prioritizing the use of evidence-based harm reduction strategies like providing naloxone and fentanyl test strips, **and what is allowed under federal, state, and local law.**
- SAMHSA is fully committed to harm reduction as part of its comprehensive approach to address addiction and the overdose epidemic. Our approach also includes expanding access to evidence-based prevention, treatment, recovery supports services.

Q: Is SAMHSA or HHS funding going to crack pipes in safe smoking kits? What else is in a safe smoking kit? When is it ever safe to smoke crack or meth?

- To answer your question directly, no federal funding will be used directly or through subsequent reimbursement of grantees to put pipes in safe smoking kits.
- The Administration is focused on a comprehensive strategy, including prioritizing the use of evidence-based harm reduction strategies like providing naloxone and fentanyl test strips, **and what is allowed under federal, state, and local law.**
- HHS is fully committed to harm reduction as part of its comprehensive approach to address addiction and the overdose epidemic. Our approach also includes expanding access to evidence-based prevention, treatment, recovery supports services.

Head Start -- Protecting Safety and Safeguarding Funds (Fraud)

TALKING POINTS:

- Protecting the health and safety of children and safeguarding federal funds are central to the Administration for Children and Families' (ACF) mission across programs.
 - HHS places the utmost priority on child health and safety; while rare, any incidents that jeopardize child safety are unacceptable.
 - HHS also takes seriously allegations of fraud, misuse and theft of federal funds.
- ACF issued guidance to Head Start programs on the requirements for reporting child incidents and provided training and technical assistance to Head Start programs on recognizing symptoms of abuse and neglect, using active supervision to create a safe environment for children, and understanding the responsibilities of a mandated reporter.
 - Recently, the Agency moved swiftly to suspend federal financial assistance in two cases based on the serious allegations of fraud, misuse and theft of federal funds.
- ACF is working diligently to implement the recommendations of the OIG in its report, *Child Safety in Head Start Programs*, and will continue to advance its rigorous national standards and reporting requirements.
 - We will continue to work with our programs to make any necessary improvements so that every child has the opportunity to thrive and reach their full potential in a safe and healthy environment. OHS will also continue to prioritize safeguarding federal funds, take all allegations about the misuse of federal funds seriously, and ensure any complaints are investigated and referred to the proper authorities if fraud is suspected.

QUESTIONS:

Q: Why did it take HHS three weeks to issue an emergency suspension in the New York case?

- The indictments did not include any allegations regarding children's safety or well-being.

Q: How many children may be impacted by the emergency suspension of these Early Head Start and Head Start programs?

- HHS is committed to minimizing the disruption to children and families impacted by this grant suspension. These grantees claimed to serve a combined total of approximately 740 children.

Q: What resources were available to assist impacted children and families?

- HHS set up a website and call hotline to assist families in finding a new early childhood program to meet their needs.

Q: What action has HHS taken to safeguard these grant funds following the indictment prior to issuing the emergency suspensions?

- On January 11, 2023, upon notification of the arrests and public release of the indictment, HHS implemented a funding lockdown on the Head Start grants for Project Social Care Head Start and NYC Early Learning Company.

Head Start - Vaccine Mandates

TALKING POINTS:

- Head Start programs are critical supports for families and children and we are committed to ensuring they remain safe and open.
- Program closures create instability for vulnerable families who depend on the program, impede Head Start families from participating in the workforce, and impose financial hardship on low wage workers.
- In January 2023, ACF published its evidence-based Final Rule on COVID-19 mitigation, which removed the universal masking requirement but did not change vaccination or testing requirements. The vaccine and testing requirements remain under review until a final rule is published to address those provisions of the Interim Final Rule with Comment Period
- The CDC continues to recommend that children ages 6 months and up be vaccinated against COVID-19. Vaccination remains the most effective way to protect individuals and the people they live and work with from getting COVID-19 – especially in care settings like Head Start.

Health Exchange Fraud

- HHS is committed to protecting taxpayer funds while balancing the burden on consumers, employers, and other individuals and entities involved in the Federally-facilitated exchange (FFE) and State-based exchanges (SBEs).
- As such, HHS has implemented a number of strategies to oversee the program integrity of Advance Payments of the Premium Tax Credit (APTC) to prevent and address instances of potential fraud.

Specifics

- As previously recommended by the GAO, HHS completed an Exchange Fraud Risk Assessment, leveraging the GAO's fraud risk framework. HHS has used this framework to identify and prioritize key areas for potential risk and mitigation activities in the Federally-facilitated exchange.
- In November 2022, HHS announced the first improper payment rate for APTC made using the Federally-facilitated exchange platform, which was less than one percent (0.62 percent) for Benefit Year 2020.
- HHS requires State-based exchanges to conduct a defined set of oversight activities, and tracks and monitors how State-based exchanges establish program integrity standards that comply with Exchange-related policy and operational requirements set forth in statute, regulations, and guidance.
- CMS regulations specify a set of eligibility verification requirements that all Exchanges, including State-based exchanges, must follow. These regulations, developed and finalized through a public comment process, allow flexibility for certain eligibility verification requirements as to how Exchanges should meet the relevant verification requirement.
- HHS monitors State-based exchange compliance with program integrity standards through numerous means, including requiring SBEs to submit annual independent external programmatic audits conducted by an independent auditing entity. State-based exchanges must inform HHS of any audit findings and submit corrective action plans to address open findings. HHS reviews the audit results and monitors open audit findings until they are resolved.
- Finally, all State-based exchanges are required to submit documented plans demonstrating that they have a comprehensive oversight and monitoring program to ensure program integrity, which includes policies and procedures to identify incidents of fraud, waste, and abuse, as required under Section 1313(a)(5) of the ACA.

Hepatitis C

(Dollars in Millions)

	FY 2024	FY 2024-2028 (5-year)	FY 2024-2033 (10-year)
National Hepatitis C Elimination Program Cost	1,134	11,337	11,337
Medicare Impact	183	1,177	984
Medicaid Impact	-1,130	-6,330	-7,180
National Hepatitis C Elimination Program Net Cost	-187	6,184	5,141

TALKING POINTS:

- **Eliminate:** We can eliminate hepatitis C in the United States over the next 5 years at minimal cost. The program will expand screening, testing, treatment, prevention, and monitoring of hepatitis C from 418,000 to 1.5 million individuals with a goal of eliminating hepatitis C in the United States.
- **Equity:** More than 2 million Americans are chronically infected with hepatitis C, including a disproportionate number of non-Hispanic Black and American Indian and Alaska Native individuals, who also experience other health disparities.
- **Rising rate of infection:** From 2010 to 2020, rates of acute hepatitis C quadrupled among adults aged 20–39 years, mirroring increasing rates of overdose deaths fueled by the nation's opioid and methamphetamine crises.
- **Curative Treatment:** Untreated, hepatitis C can cause advanced liver disease, liver cancer, and death. An 8 to 12-week course of oral direct acting antivirals cures hepatitis C in more than 95% of people. Curative treatment prevents ongoing transmission, reduces the incidence of liver cancer, saves lives, and is cost effective.
- **Prevention:** Implementation of the program will increase the number of people treated for hepatitis C from 418,705 to 1,500,452 over 5 years, preventing hundreds of thousands of severe illnesses, tens of thousands of serious complications, and many thousands of lives over the next decade – at minimal net cost.

QUESTIONS:

Q: How will this program work?

A: The Program includes a national subscription model to expand access of direct acting antivirals to Medicaid beneficiaries, justice-involved populations, uninsured individuals, and American Indians and Alaskan Natives receiving care through the Indian Health Service, tribal health, or urban Indian health programs. The subscription model will include all manufacturers that offer competitive prices.

For Medicaid beneficiaries, the federal government will pay 100% of the medication costs through the subscription program. The medications will be made available through established

distribution channels, including mail order pharmacies, retail pharmacies, and 340B hospital and clinic pharmacies. The model will include a low burden eligibility check, likely at the provider level, to avoid waste, errors, and fraud.

For Medicare beneficiaries, the federal government will cover 100% of cost-sharing for all Medicare Part D beneficiaries receiving covered treatment. Medicare will also adopt a program of quality measurement and improvement to drive uptake of hepatitis C testing and treatment.

Private insurers will be required to cover hepatitis C testing and curative hepatitis C treatment by reducing coverage denials and meeting network adequacy requirements. Insurers will also limit out-of-pocket costs for these medications; for example, by including coverage prior to the deductible being met.

Q: Is this a cure for hepatitis C?

A: There is still no vaccine for hepatitis C. The program will include support for vaccine research and preventive services, which has been shown to reduce reinfection rates substantially.

Q: How will HHS identify and attract currently infected individuals to get screened, tested, and treated?

A: The Program will substantially expand screening strategies and settings, especially for high-risk populations. For instance, it will support universal screening in primary health care settings as part of routine care, including through automatic prompts to clinicians in electronic health records.

The program will also develop educational resources for providers and the public to increase awareness of hepatitis C, screening recommendations, and treatment options.

Other approaches will include expanding the number of providers who can screen and treat hepatitis C using proven and innovative telehealth methods and increasing the number of community health workers and case managers who can successfully link people to care. CDC and HRSA will provide grants to state and local health departments to support the funding for community-based providers. The Program will also support mobile treatment capabilities.

The Program will accelerate the commercialization of diagnostic tests that are available outside of the United States, specifically point-of-care RNA diagnostics and hepatitis c virus core antigen laboratory assays.

Q: How many non-Hispanic Black and American Indian and Alaska Native individuals, experience other health disparities?

A: Hepatitis C disproportionately affects certain populations, many of which experience other health and social inequities -- including those who are uninsured, American Indian and Alaska Native persons, non-Hispanic Black persons, those caught up in the opioid crisis, and baby

health records. boomers who were infected in pre-1993 blood transfusions. From 2010 to 2020, rates of acute hepatitis C quadrupled among adults aged 20–39 years, mirroring increasing rates of overdose deaths fueled by the nation's opioid and methamphetamine crises.

Q. Which parts of HHS will carry out the work on this program?

A: The Office of the Assistant Secretary for Health (OASH) will administer and coordinate this whole-of-government program. With a robust organizational structure in place, OASH is well positioned to ensure cross-departmental and intergovernmental collaboration and transparency. In similar capacity, OASH also leads and coordinates a cross-agency, federal government-wide the Ending the HIV Epidemic in the U.S. (EHE) initiative. OASH will also be responsible for providing an annual report to Congress.

HIPAA

TALKING POINTS:

- Ensuring individuals have access to their health information and protecting patient privacy is of the utmost importance.
- OCR expects to receive over 33,000 HIPAA complaints this year and has seen an increase in large breaches (over 500 people).
 - HIPAA complaints increased 39 percent from 2017 to 2022; HIPAA breach cases alone have increased 259 percent during the same time.
- OCR's proposed budget increase to \$78 million will also allow the division to fully enforce the law and keep up with the growing workload of cases through hiring additional investigators.
- OCR is also currently engaged in the rulemaking process on the HIPAA Privacy Rule, which established federal standards for the protection of protected health information, and we look forward to your feedback during that process.

IHS - Provider Abuse

TALKING POINTS:

- There is no more important priority at IHS than the protection of patients – especially our most vulnerable patients – from abuse and instilling a culture of accountability. IHS must be able to continue to foster trust and instill confidence in the communities it serves.
- IHS has taken strides to increase safety across the board during this Administration.
 - The IHS Anti-Abuse policy is nearing completion. This policy will increase protection for all patients, and will cover all employees, and all types of abuse.
 - The IHS is developing and implementing a uniform credentialing and privileging policy.
 - The IHS has also fully implemented Safety Tracking & Response (I-STAR) across the Agency to provide real time data on any reported provider abuse, which will result in immediate action to investigate any provider abuse allegations.
- We can still do more. We continue to review our systems and identify gaps that could lead to vulnerabilities. IHS is committed to working with Congress, HHS OIG and local enforcement agencies, and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of the patients under our care. The budget includes an additional +\$12 million for IHS Direct Operations to support critical management and oversight functions at IHS, including implementing recommendations to prevent abuse and ensure patient safety.

QUESTIONS:

Q: Can you speak to the lessons learned after the Dr. Weber tragedy?

My heart goes out the victims of this unfortunate tragedy. Abuse and other forms of criminal misconduct should not be tolerated

HHS Employees are encouraged to report any suspected unethical or criminal behavior. Any transgressions that endanger the people we serve or violate the public trust will be held accountable.

We are committed to maintaining transparency with Congress as IHS and other HHS officials work to implement important and necessary changes to ensure the safety of our workplace and patients.

The safety and wellbeing of children in the care of HHS is among our most important responsibilities and we will continue to be vigilant.

Q: What does IHS have to say to the victims of provider abuse?

- The IHS acknowledges the trauma suffered by the victims of sexual abuse within our agency is unacceptable. These actions are reprehensible, and we sincerely regret the harm caused to those involved.
- We will do all we can to improve and sustain the culture of care throughout the IHS. The agency is committed to working with Congress and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of every child. Together, we are moving forward in delivering quality care to achieve the IHS mission to raise the physical, mental, social and spiritual health of American Indians and Alaska Natives to the highest level

Q: What are the 11 actions that IHS intends to accomplish with the goal of removing IHS from the GAO's High-Risk List?

Misconduct and Performance Policy and Training Review
Design Governing Board Standardization
Assess Needs of Patient Populations
Document Oversight of Facility Budgets
VA and IHS MOU Performance Measures
Strategic Plan Implementation and Progress Tracking
Improve Internal Communications
Document Oversight of Leadership Training
Design a Policy Review Process
Create a Culture of Compliance
Improve Oversight of Regional and Area Human Resources Offices

IHS - Advance Appropriations

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Total IHS Funding	7,105	9,650	+2,545*

* Represents an increase of 36% over FY23 enacted

TALKING POINTS:

- We are especially grateful for your work providing IHS advance appropriations in the FY 2023 bill – this was truly a historic achievement that will greatly improve the lives of Native American families throughout Indian country.
 - Indian Country has been asking for more stability to address the persistent health disparities suffered by AI/ANs, and together, we finally delivered.
- Advance appropriations represent an important step towards securing stable and predictable funding to improve the overall health status of AI/ANs, and ensuring that the disproportionate impacts experienced by tribal communities during government shutdowns and continuing resolutions are never repeated.
 - We are already seeing the benefits of advance appropriations in action – we have heard from health facilities about benefits in improved planning and staff job security.
- IHS remains committed to upholding promises it has made to both Congress and Indian Country to continue to increase accountability and improve the quality of care for patients.

QUESTIONS:

Q: What about mandatory funding?

- Looking beyond this budget year, the Administration continues to support full mandatory funding for IHS as the more appropriate long-term funding solution for the agency.
- We will continue to work collaboratively with Tribes and Congress to move toward sustainable, mandatory funding.
- Until this solution is enacted, it is critical that Congress continue to prioritize advance appropriations for IHS through the discretionary appropriations process to ensure funding for healthcare services and critical facilities activities are not disrupted.
- Beginning in FY 2025, the budget would make all funding for IHS mandatory. Funding would grow automatically to account for a number of factors.
 - We believe that a change of this magnitude is needed to meet the moment and deliver for Indian Country.

IHS – Contract Support Costs

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Contract Support Costs*	969	1,168	+199

*The budget proposes mandatory funding for Contract Support Costs in FY 2024

TALKING POINTS:

- We are aware of recent court rulings that would require IHS to pay Contract Support Costs on portions of Tribally-operated Health Programs funded by third party revenues like Medicare and Medicaid reimbursements.
- This change could significantly increase the amount of Contract Support Costs that IHS provides to Tribally-operated Health Programs.
- If these rulings are upheld, HHS will work to implement them as expeditiously as possible.

QUESTIONS:

Q: Does the FY 2024 Budget take the cost of implementing these rulings into account?

- The funding estimate for Contract Support Costs in the budget does not reflect the impact of implementing the 9th and 10th circuit court rulings, as they are not yet settled case law.
- HHS is actively monitoring the situation and analyzing potential costs. We will keep Congress apprised of any changes in Contract Support Costs as a result of the rulings.

IHS - High-Risk List

TALKING POINTS:

- IHS is committed to addressing and correcting past failings. We also remain committed to transparency and accountability and are continually working to sustain and improve the culture of care throughout the Agency.
- In 2021, IHS developed an action plan to meet the GAO's criteria for removal from its high-risk list. Since that time, the agency has been working to address actions to accomplish by the end of June 2023. IHS leadership is committed to making progress on addressing GAO's recommendations. These efforts built the foundation for the agency's 2023 work plan.
- The Department and the Agency are committed to working with Congress and tribal and urban Indian organization leaders across the nation to ensure we can protect the health and wellbeing of every patient. Together, we are moving forward in delivering quality care to achieve the IHS mission to raise the physical, mental, social and spiritual health of American Indians and Alaska Natives to the highest level.

QUESTIONS:

Q: What are some of the actions that IHS intends to accomplish with the goal of removing IHS from the GAO's High-Risk List?

Misconduct and Performance Policy and Training Review
Design Governing Board Standardization
Assess Needs of Patient Populations
Document Oversight of Facility Budgets
VA and IHS MOU Performance Measures
Strategic Plan Implementation and Progress Tracking
Improve Internal Communications
Document Oversight of Leadership Training
Design a Policy Review Process
Create a Culture of Compliance
Improve Oversight of Regional and Area Human Resources Offices

Q: GAO highlighted that IHS faces workforce challenges; their overall vacancy rate for clinical care providers was 25 percent at one point. What has IHS done to resolve this issue?

- IHS has strengthened its relationship with academic institutions through fellowships, residencies and clinical rotations that attracted talented practitioners focused on generating positive change in Indigenous communities.

- IHS signed a new MOU with the VHA aimed at improving the health status of AI/AN veterans.
- IHS has supported public health workforce activities to bolster the capacity of tribal communities to respond to future emergencies.

Q: What has IHS done to address some of the concerns with personnel processes and systems?

- Implemented a nationwide electronic provider credentialing system that modernizes provider credentialing and privileging within federally-operated hospitals and clinics.
- Implemented an employee relations case tracking system to manage nationwide employee relations activities.
- Implemented an electronic Security Manager System to track personnel background investigations.
- Established a standardized procedure for determinations of unsuitability from a background investigation.

Institution for Mental Disease (IMD) Waivers

TALKING POINTS (IMDs AND CRISIS STABILIZATION):

- Strengthening behavioral health care is a top priority for the Biden-Harris Administration. That's why last year, as part of the National Tour to Strengthen Mental Health, I traveled along with other HHS leaders across the country to hear directly from Americans about the mental health challenges they're facing and engage with local leaders to strengthen the mental health and crisis care systems in our communities.
- Under current law, Medicaid generally does not pay for services rendered to beneficiaries aged 21 to 64 who are patients in psychiatric institutions with more than 16 beds, referred to in Medicaid as "institutions for mental disease" (IMDs).
- Crisis stabilization services are critical to those experiencing a behavioral health crisis, and HHS shares your goal of ensuring Medicaid beneficiaries have access to a continuum of crisis stabilization services. CMS has worked within the confines of the law to provide states with flexibility to increase access to these services. For example,
 - o CMS has approved Medicaid section 1115 demonstrations that allow state Medicaid programs to pay for services provided to individuals with serious mental illness or serious emotional disturbance or substance use disorder who are short-term residents in an IMD.
 - o Similarly, managed care organizations are permitted to reimburse up to 15 days per month of treatment in IMDs.

If Pressed on Qualified Residential Treatment Programs

- Children in foster care should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. CMS is committed to ensuring children with unique health needs receive high-quality care in the most appropriate setting permissible under the law.

QUESTIONS:

Q: Are crisis stabilization programs subject to the Medicaid IMD exclusion?

- Each state is responsible for determining whether a facility is an IMD. If a state Medicaid agency determines that a facility is an IMD, federal financial participation generally would not be available for any services provided to Medicaid beneficiaries ages 21-65 while residing in that facility. Medicaid does permit payment for inpatient psychiatric hospital services provided to those over the age 65 or under the age 21.

Q: Can you explain how the IMD exclusion doesn't violate parity laws? Enrollees are covered if they stay in non-psychiatric facilities that have more than 16 beds. Are private insurance plans allowed to make this exclusion?

- The payment exclusion for Medicaid services provided to beneficiaries in IMDs is a statutory prohibition established by the Congress in 1965 and therefore beyond the scope of existing HHS authority. Under this broad exclusion, federal financial participation is generally unavailable for the cost of services (regardless of whether the services address physical or mental health) provided either inside or outside the IMD while the individual is a patient in the facility. The full range of covered services, including mental health and substance use disorder services, could be paid by Medicaid when beneficiaries are in facilities that are not IMDs.

Q: Do you believe that children in Qualified Residential Treatment Programs with more than 16 beds should be able to keep their Medicaid coverage?

- Children should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. Placement in a Qualified Residential Treatment Program that is an IMD does not impact Medicaid eligibility.
- While the Medicaid statute prohibits states from receiving federal financial participation for services delivered to most individuals residing in an IMD, states can apply for a time-limited serious mental illness/serious emotional disorder 1115 demonstration to receive Medicaid payment for services provided to children in Qualified Residential Treatment Programs with more than 16 beds.

Infant Formula

TALKING POINTS:

- Ensuring that safe and nutritionally adequate infant formula is available to parents and caregivers across the country is a top priority of the Department.
- That is why during the shortages—HHS invoked the Defense Production Act to ensure rapid increase in supply. We flew in **Xlbs** of infant formula, facilitated **X** flights to fly in formula to the United States.
- FDA is focused on hiring additional staff, modernizing scientific requirements, and streamlining review processes for infant formula.
- This budget will support FDA efforts to implement new authorities provided by the FY23 omnibus including **requiring prompt notifications of disruptions** to manufacturing, requiring redundancy risk management plans to **enhance resiliency** and mitigate future supply chain disruptions, increasing the frequency of inspections, and developing a **National Strategy on Infant Formula**.

QUESTIONS:

Q: How will FDA ensure the infant formula crisis does not happen again?

- FDA continues efforts to ensure the availability of safe, nutritious infant formula.
- The FY 2024 President's Budget includes a request for an additional \$10 million, for a total of \$21million, to support additional hiring of staff, as well as IT investments to better address current and emerging infant formula safety and supply issues.
- This budget will support FDA efforts to implement new authorities provided by the FY23 omnibus including requiring prompt notifications of disruptions to manufacturing, requiring redundancy risk management plans to enhance resiliency and mitigate future supply chain disruptions, increasing the frequency of inspections, and developing a National Strategy on Infant Formula.
- FDA also released a transition plan guidance for industry to outline a path for interested manufacturers that are marketing infant formulas in the U.S. under enforcement discretion to bring those products into compliance with U.S. requirements, helping the U.S. continue to diversify its infant formula market. As part of this plan, the Agency also continues to exercise enforcement discretion for certain manufacturers to import safe and nutritionally adequate infant formula.
- FDA also continues to work with industry to increase the volume of infant formula through normal production channels, as well as increase its monitoring of online marketplaces for fraudulent infant formula products.
- FDA also sent a letter to the powdered infant formula industry calling for prompt action to improve processes and programs to enhance safety measures.

Q: How will FDA's organizational changes improve its ability to oversee the infant formula supply chain and carry out its food safety responsibilities?

- FDA is implementing a new, transformative vision for the FDA Human Foods Program, which will focus on protecting and promoting a safe, nutritious U.S. food supply that more quickly adapts to an ever-changing and evolving environment.
- This proposal will unify the Human Foods Program and empower a new Deputy Commissioner for Human Foods.
- The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk prioritization.

Inflation Reduction Act (IRA)

TALKING POINTS:

- Thanks to the Inflation Reduction Act, we finally have the authority to get American families the lower prescription drug costs they deserve.
- At the beginning of this year, we implemented the \$35 cost-sharing cap for insulin in Medicare Part D and eliminated cost-sharing under Part D for recommended, preventive vaccines.
- We are also pleased that the IRA included a provision to expand low-income assistance and to cap Part D annual out-of-pocket drug costs at \$2,000 in 2025.
- Earlier this month, we released guidance outlining how we will approach the law's landmark provisions permitting Medicare to negotiate prices for the first time, seeking comment on many key policies.

INSULIN PRICING TALKING POINTS:

- As of this week, all three of the leading insulin producers in America have heeded President Biden's call to reduce their prices and cap the cost of insulin to \$35 per month.
- This is a major victory for seniors and working families. For far too long, American families have been crushed by drug costs many times higher than what people in other countries are charged for the same prescriptions.
- Last August, President Biden signed into law the Inflation Reduction Act, which for the first time allows Medicare to negotiate lower prescription drug prices for seniors, caps the cost of insulin at \$35. During his State of the Union, the President made clear that this life saving benefit should apply to everyone – no American should have pay more than \$35 for insulin. And he called for extending the \$35 monthly cap on insulin to all Americans.

QUESTIONS:

Medicare Drug Price Negotiation Program

Q: Won't the Medicare Drug Price Negotiation Program lead to manufacturers increasing the launch prices for new drugs?

- Manufacturers use many factors when considering their launch prices and will price their drugs at the price they believe the market will bear.
- It's also important to note that a drug cannot be eligible for negotiation until it has been FDA-approved for at least 7 years and a biological product cannot be eligible for negotiation until it has been FDA-licensed for at least 11 years.
- The Congressional Budget Office didn't estimate that the new Drug Price Negotiation program would have a significant impact on launch prices.

Q: Will drug price negotiation have a chilling effect on manufacturers seeking a second or third indication for an orphan drug?

- Drugs selected for negotiation will have been on the market for quite some time and will be high expenditure drugs.
- The law requires that at least 7 years, for drugs, or 11 years, for biologicals, must have elapsed between the selected drug publication date and the FDA approval or licensure, as applicable.
- We support innovation and believe it is vitally important that beneficiaries have access to innovative new therapies.
- Increased competition as a result of drug price negotiation will encourage drug makers to innovate in order to stay competitive and broaden their target patient populations, including orphan diseases.

Q: Won't drug price negotiation crush innovation and kill hundreds of new cures? Studies have found that the IRA's negotiation provision would kill up to 342 cures.

- We support innovation and believe it is vitally important that beneficiaries have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations.
- The Negotiation Program will make drugs more affordable for people with Medicare. We're also expecting negotiation to encourage drug makers to create business models to stay competitive, fostering the development of new treatments and delivery methods.

Q: What concrete steps does the Administration plan to take in order to implement and enforce the legislation's ban on the use of discriminatory comparative effectiveness research (i.e., QALYs)?

- The law requires that we not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who are elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. We will follow the law.

Medicare Part B and Part D Inflation Rebates

Q: How will HHS plan for and respond to drug shortages or severe supply chain disruptions of Part B and Part D rebatable drugs?

- The law requires CMS to waive or reduce the inflation rebate when drug shortages or certain supply chain disruptions occur.
- CMS is soliciting comment on this issue, and intends to design a final policy that preserves access, while not creating perverse incentives for drug companies to sustain or create drug shortages.

Q: Won't the Medicare Prescription Drug Inflation Rebate Program lead to manufacturers increasing the launch prices for new drugs?

- Our understanding is that manufacturers use many factors when considering their launch prices and price their drugs at the price they believe the market will bear.

- For too long, Americans have faced skyrocketing prescription drug prices.
- Thanks to the law, prescription drug companies will pay a rebate for increasing their prices above inflation, paid into the Medicare Trust Fund.
- This policy will strengthen the Medicare program for generations to come.

Q: Are 340B acquired units being removed from the Part D inflation rebates?

- The Inflation Reduction Act sets clear parameters and timeframes for how to treat 340B drugs as HHS implements inflation rebates. We will follow the law.
- The Inflation Reduction Act requires that 340B units be excluded from calculating Part D inflation rebates beginning in 2026. We will follow the law.

Implementation Funding

Q: How is HHS planning to spend the \$3 billion in implementation funding provided by the Inflation Reduction Act for the Drug Price Negotiation Program?

- We're still in the early stages of the implementation process.
- The new Drug Price Negotiation Program requires a great deal of new work by CMS.
- We're using the funding to hire new staff, bring on contractors, and develop and modify systems.

Q: What specific measures does the administration plan to undertake in order to prevent waste, fraud, and abuse with respect to the implementation funding?

- We take our responsibility to protect taxpayer dollars very seriously. We are vigilant about how we are spending the funding to head off waste, fraud, and abuse, just as we do with implementing other programs.

LGBTQ Youth

TALKING POINTS:

- Gender affirming care is a **standard of care**. It's also mental health and suicide prevention.
- The current medically-accepted standard of care, WPATH SOC8, was developed by the top medical and scientific experts in transgender health. The standard of care is based on a significant body of evidence and is supported by [most major medical associations](#).
- The ideologically-driven attacks on gender-affirming care do not account for the best available science and evidence on appropriate healthcare services for transgender people.
- Likewise, gender affirming care is an integral part of child centered welfare programs especially those for vulnerable children and youth. This budget supports prohibiting child welfare agencies from discriminating against current or prospective foster or adoptive parents or a child in foster care on the basis of sexual identity, gender identity, or expression.

QUESTIONS:

Q: What is a woman?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- Support youth and families; HHS commitment to advance safety and support for LGBTI+ youth. Access to gender affirming care, when medically necessary can be lifesaving.
 - Ensuring such access is the law.

Q: How many genders are there?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- At HHS, we are committed to advancing health equity for people of all genders. Health equity is defined by HHS Healthy People 2030 as the "attainment of the highest quality of health for all people." We work toward that goal every day.

Q: Does HHS support irreversible genital surgeries on children?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

Q: Is HHS funding gender affirming care?

- The Department is committed to removing discriminatory barriers to coverage for all because it can lead to improved health outcomes for all, including those in the LGBTQI+ community.
- HHS will continue to interpret and enforce section 1557 of the ACA and its protections against sex discrimination to prohibit discrimination on the basis of sexual orientation and gender identity in all aspects of health insurance coverage to which Section 1557 applies.

Q: Does HHS support “biological boys” playing on girls sports teams?

- In my role as Secretary of Health and Human Services, I am focused on making sure people have health care, period. HHS does not have a role in youth sports.
- [Optional]: The harm caused by these state laws is very clear: trans youth are more likely to experience social isolation, loneliness, depression, and are more likely to utilize tobacco, alcohol, and other drugs – all of which we know are decreased by participation in school sports.

Q: Does HHS support irreversible and experimental medicine on children such as puberty blockers?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

LIHEAP/LIHWAP

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Base Funding	4.0B	4.1B	+111M
Supplementals	2.1B	100M	-2.0B
Total LIHEAP Program Level	6.1B	4.1B	-1.9B

* LIHWAP's last funding was in FY21 at \$638 million under the Consolidated appropriations Act of 2021. The American Rescue Plan appropriated an additional \$500 million in emergency funds to LIHWAP

TALKING POINTS:

- We recognize that LIHEAP is an essential program for Americans, especially for older adults and people with disabilities who are particularly vulnerable to the effects of cold.
- Likewise, LIHWAP benefits vulnerable households that pay the greatest proportion of their income towards their home drinking water and wastewater services. Water, heat, and especially in a changing climate – cooling – are basic human rights that the Department is proud to help make accessible for all.
- We have made historic investments in the program during the Biden Administration.
 - In FY2023, Congress appropriated more than \$6.1 billion for LIHEAP.
 - In the past month we have disbursed over \$1.5 billion of these funds to our 206 LIHEAP grant recipients – a lifeline for many seeing record cold and snowfalls this winter.
- The Budget requests \$4.1 billion for LIHEAP, an increase of \$111 million in base funding compared to FY 2023
- We are looking forward to continuing to partner with you to ensure we meet the critical mission of these programs by providing it with strong funding levels.

QUESTIONS:

Q: There has been some reporting and concern that states will not be able to spend their LIHWAP disbursements in time and leave money on the table. Can you speak to what the Department is doing to support states in this effort?

- We are conducting Spend Down Calls with each state, to provide TTA and help identify solutions to maximize spending when needed. We want to make sure states know about and are able to talk through promising practices that can help increase their spending rates before we take back any funding for reallocation.

Q: Why did it take HHS a couple of months to release these funds?

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- The delay in releasing the funding is largely due to the fact LIHEAP funding was split across multiple funding streams in the final budget, including three different supplementals.
- HHS worked to find the most efficient and expedient way to release funding while minimizing the reporting burden to the grant recipient to the greatest extent possible.

Long Term Care

TALKING POINTS:

- The budget invests an additional \$150 billion in Medicaid home and community-based services over 10 years, enabling older adults and people with disabilities to remain in their homes and stay active in their communities.
- The Medicaid investments are complemented by a robust agenda to **improve the safety and quality of nursing home care**, including efforts to improve ownership transparency, increase inspections of low-performing nursing homes, and expand financial penalties for substandard facilities.
- The budget makes a \$566 million discretionary investment in CMS's survey and certification program to provide **adequate funding for nursing home inspections** and address the backlog of complaint surveys, a \$159 million increase.

QUESTIONS:

[See CMS Medicaid Budget Summary for specific questions on Home and Community-Based Services.]

Q: CMS is proposing a number of mandatory nursing home proposals. Why is an increase in discretionary funding also necessary?

- Since FY 2015, CMS has seen an increase in the overall number of nursing home complaints and instances of high-level violations, both of which require additional survey resources. Additional resources allow CMS and state survey agencies to maintain a more proactive, rather than reactive, oversight posture that promotes patient safety and quality.

Q: Won't penalizing poor performing facilities strain resources and limit a facility's ability to provide high-quality care, further perpetuating the issue?

- Tens of billions of federal taxpayer dollars flow to nursing homes each year, and too many continue to provide poor, sub-standard care that leads to avoidable resident harm.
- Federal taxpayer dollars should not flow to nursing homes that are unsafe.

March In Rights

TALKING POINTS:

March-in authority is a powerful tool designed to ensure that the benefits of the American taxpayer's investment in research and development are reasonably available to the public. It is critically important for us to thoroughly understand where the boundaries of that authority lie in order to carry out that authority effectively.

Consistent with President Biden's Executive Order on Promoting Competition in the American Economy, the DOC has not finalized any provisions on march-in rights in the proposed rule "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions" that would have prohibited the government's use of march-in rights solely on the basis of product pricing.

As a first step in reviewing its march-in authority, HHS, DOC, and other agencies will develop a framework for implementation of the Bayh-Dole march-in provision that clearly articulates guiding criteria and processes for making determinations, including where pricing is a factor in agencies' assessments.

Questions

Q: What is the total cumulative support provided by the NIH to Moderna, including for clinical trials? How much money has the US government provided to Moderna to research, develop and distribute the COVID-19 vaccine?

HHS/NIH/NIAID has provided no direct financial support to Moderna for the development of the mRNA-1273 COVID-19 vaccine. NIAID scientists collaborated with Moderna to design and test the mRNA-1273 COVID-19 vaccine.

NIH did not fund Moderna directly but NIH fully funded Phase I clinical trials through existing clinical trial networks, and supported extramural institutions during OWS-funded Phase 3 clinical trials.

Note that the COVID-19 vaccine product licensed and manufactured by Moderna contains IP beyond the patents shared with NIH. This includes IP that belongs to Moderna, e.g., the lipid nanoparticle technology.

Q: What was HHS thinking when negotiating these patents?

HHS's top priority during the COVID-19 pandemic was establishing safe and effective medical countermeasures that would save lives and prevent human suffering from COVID-19.

This strategy included leveraging a preexisting partnership with Moderna and the NIAID Vaccine Research Center (VRC) that had been established for the development of mRNA-based vaccine candidates against selected pathogens, including the coronavirus that causes Middle East respiratory syndrome (MERS).

This partnership resulted in the development of an investigational vaccine against MERS. At the time of negotiations, it was unclear whether mRNA-based vaccines would be successful, NIH priorities were in line with what NIH has expertise in, the science –

ensuring the vaccine worked and those results were reliable, therefore NIH negotiated according to the science and the pressing public health need that:

A single IRB would be used for all trials, to ensure rapid and consistent research

Similar endpoints across trials, to facilitate comparison of trial results

Access to data that allowed evaluation of those endpoints

Maternal Health Initiative

(Dollars in Millions)

Agency	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
AHRQ	--	7	+7
CDC	97	148	+51
HRSA	157	276	+119
IHS	7	10	+3
NIH ¹	30	30	--
Total	291	471	+180

1/ Does not include costs NIH would assume as one-time for Implementing a Maternal health and PRenancy Outcomes Vision for Everyone initiative.

TALKING POINTS:

- The FY 2024 budget includes \$471 million to continue HHS's longstanding efforts to **reduce maternal mortality and morbidity** rates; expand maternal health initiatives in rural communities; implement implicit bias training for healthcare providers; create pregnancy medical home demonstration projects; and address the highest rates of perinatal health disparities, including by supporting the perinatal health workforce.
- The U.S. has the **highest maternal mortality rate** among developed nations, with a higher proportion effecting Black and American Indian/Alaska Native women. HHS is working to **end these race-based disparities and address adverse maternal health outcomes** by supporting programs that address implicit biases, investing in innovative strategies to achieve equitable maternal care, establishing a diverse workforce, and ensuring federal funded activities focus on equal treatment, inclusion, and accessibility.
- HHS's maternal health initiatives **addresses this significant public health problem**. Investments focus on four strategic goals: 1) healthy outcomes for all woman of reproductive age, 2) healthy pregnancies and births, 3) optimizing postpartum health; and 4) improving data and bolstering research.

QUESTIONS:

Q: What investments have HHS made in the last fiscal year to address the nation's overall maternal health?

- HHS approved the extension of Medicaid and Children's Health Insurance Program (CHIP) coverage for 12 months after pregnancy. An estimated 333,000 Americans annually in 23 states and D.C. are now eligible for 12 months of postpartum coverage. If all states adopted this option, as many as 720,000 people across the United States annually would be guaranteed Medicaid and CHIP coverage for 12 months after pregnancy.

- HHS also invested investing \$8.5 million in initiatives designed to reduce pregnancy-related deaths and complications that disproportionately impact minority populations and those living in rural areas.
- HHS also awarded \$337 million to 56 states, territories, and nonprofit organizations through its Maternal, Infant, and Early Childhood Home Visiting Program to support communities and provide voluntary, evidence-based home visiting services to women during pregnancy, and to parents with young children up to kindergarten entry.

Medicare Coverage of Innovative Technology (MCIT) and Transitional Coverage for Emerging Technologies (TCET)

TALKING POINTS:

- HHS is committed to making sure people with Medicare are able to benefit from innovative, emerging technologies.
- HHS, through CMS, remains committed to establishing an expedited Medicare coverage pathway that achieves timely and predictable coverage of medical devices while at the same time ensuring that coverage is based on scientifically sound clinical evidence.
- HHS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections.

If asked about FDA/CMS authorities:

- The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) have different legal authorities to use when considering product approvals and coverage. Generally, the FDA makes approval decisions based on whether a product is safe and effective while CMS makes coverage decisions based on whether something is reasonable and necessary for the treatment of an illness or injury for the Medicare population.
- These two processes are separate and run independently by the two agencies.
- Unlike traditional approval – FDA's accelerated approval pathway does not require finding that a new product has a clinical benefit; in other words, granting accelerated approval does not tell CMS that a product is effective.
- Therefore, when CMS considers coverage of an accelerated approval product, CMS has to decide whether it is reasonable and necessary without the benefit of an FDA finding of effectiveness. CMS has to weigh the potential benefits – if any – of coverage against any risks or dangers.

QUESTIONS:

Q: Why did CMS repeal the January 2021 Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (R&N) final rule?

- The January 2021 final rule established a coverage commitment for breakthrough devices without requiring demonstration of a health benefit in the Medicare population.
- Additionally, stakeholders were concerned that a codified definition of reasonable and necessary would remove existing flexibility and potentially impact the ability for CMS to ensure equitable health care access for all people with Medicare.

- We believe it is important to solicit additional feedback on this topic. We look forward to continuing to engage with a wide number of stakeholders as we determine appropriate next steps that are in the best interest of people with Medicare and the program overall.

Q: Didn't CMS stifle innovation and limit access to new technologies by repealing the January 2021 MCIT/R&N final rule? Why can't Medicare just cover what the FDA approves?

- The repeal of the January 2021 MCIT/R&N final rule does not mean an item or service is not covered. Devices may still be covered through claim-by-claim determinations, one or more local coverage determinations, or a national coverage determination. The standard for Medicare coverage is not synonymous with the standards for FDA marketing authorization of devices, which are not specific to the Medicare population.
- While the FDA generally reviews a device to ensure it meets the applicable safety and effectiveness standard, there is often limited evidence regarding whether the device is clinically beneficial to Medicare patients.
- Evidence on whether or not a device is clinically beneficial to Medicare patients is a key factor in determining national coverage under Medicare.

Q: What has CMS done since the January 2021 MCIT/R&N final rule was repealed? Why is it taking so long for CMS to release the proposed TCET rule providing for a new expedited coverage pathway?

- CMS remains committed to establishing an expedited Medicare coverage pathway that achieves timely and predictable coverage of medical devices while at the same time ensuring that coverage is based on scientifically sound clinical evidence.
- CMS continues to work closely with patient groups, medical professionals and societies, medical device manufacturers, other federal agencies (including the FDA), and others involved in developing innovative medical devices as it moves policy forward.

MA Prior Authorization Rules

TALKING POINTS:

- In December 2022, CMS issued the Advancing Interoperability and Improving Prior Authorization Processes proposed rule that would modernize the health care system by requiring certain payers—including Medicare Advantage organizations—to implement an electronic prior authorization process, shorten the time frames for certain payers to respond to prior authorization requests, and establish policies to make the prior authorization process more efficient and transparent.
- The proposed rule would address challenges with the prior authorization process faced by providers and patients.

QUESTIONS:

QA regarding support for Improving Seniors' Timely Access to Care Act (or generalized for other prior auth legislation)

- In December 2022, CMS issued proposed rules that would streamline prior authorization processes and improve prior authorization in Medicare Advantage to help Medicare Advantage enrollees have timely access to medically necessary care.
- We are grateful for your leadership on this important issue, including your work on the Improving Seniors' Timely Access to Care Act, and look forward to continuing to work with you and with Congress to make the prior authorization process more efficient and transparent in Medicare Advantage. HHS always appreciates the opportunity to provide technical assistance to Congress on important health care issues.

Medicaid Disproportionate Share Hospital (DSH) Proposed Rule

Talking Points

- In February 2023, CMS issued a proposed rule that would implement statutory changes made by the Consolidated Appropriations Act of 2021 to update the methodology for the calculation of the hospital-specific DSH limit.
 - The law modified the calculation of the Medicaid portion of the hospital-specific DSH limit to include only costs and payments for services furnished to beneficiaries for whom Medicaid is the primary payer for such services. Accordingly, the limit excludes costs and payments for services provided to Medicaid beneficiaries with other sources of coverage, including Medicare and commercial insurance.
- Additionally, the proposed rule would enhance administrative efficiency by making technical changes and clarifications to the DSH program.
- CMS is seeking public feedback on this proposal and will closely review the comments they receive as they move forward with the decision-making process.

Medicaid Health Taxes Guidance

TALKING POINTS:

- In February 2023, CMS issued an informational bulletin reiterating federal requirements concerning health care-related taxes and hold harmless arrangements involving the redistribution of Medicaid payments.
- HHS recognizes that health care-related taxes often finance critical programs that pay for care provided to Medicaid beneficiaries and shore up the health care safety net.
- HHS will continue to approve permissible health care-related taxes that meet federal requirements and remains committed to working with states.

Medicare HI Trust Fund Solvency

TALKING POINTS:

- The FY 2024 legislative proposed law package extends Medicare Trust Fund solvency by at least 25 years, without cutting benefits.
- We achieve this by:
 - Directing all revenues from the net investment income tax, including tax code reforms that ensure high-income earners pay their fair share into the Medicare Hospital Insurance (HI) Trust Fund.
 - Crediting savings from prescription drug reforms to the HI Trust Fund.

QUESTIONS:

Q: How much of this plan is just general revenue transfers/gimmicks?

- This plan increases Medicare solvency by ensuring that revenues going into the HI Trust Fund are sufficient to cover benefits. We achieve that by asking high-income people to pay a little more, achieving savings to Medicare from lowering the cost of drugs, without cutting benefits, and putting revenue that should have always gone to Medicare back where it belongs. Nothing about this proposal is a gimmick.
- The President fundamentally disagrees with those who believe that a conversation about Medicare should be a conversation about cutting benefits to seniors. His Budget shows that we can improve solvency while reducing seniors' costs – unless Congress takes revenues and prescription drug reforms off the table.
- *If pressed on general revenue transfers specifically:* The revenue from the Net Investment Income Tax was always intended to help strengthen Medicare. Fulfilling that purpose is both appropriate and important. Moreover, the large majority of the savings in this proposal come from new revenues and new prescription drug savings.

Q: Does your Budget double count the Medicare solvency provisions?

The Budget appropriately and transparently accounts for the impact on both the unified Budget and the Trust Funds, in exactly the way that the Congressional Budget Office and all other scorekeepers do.

Q: Are the tax proposals consistent with the President's \$400,000 pledge?

Yes. Nothing in the President's Budget raises taxes on people making less than \$400,000.

Q: Is this an opening bid for a real negotiation with Republicans over Medicare solvency as part of debt limit discussions?

- First, let me reiterate the President's stance on the debt limit: the full faith and credit of the United States is not up for negotiation, and Congress needs to do its job and increase the debt limit without conditions.

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- The President is including a plan to strengthen Medicare in his Budget because it's part of his vision for the nation's economic and fiscal future.
- He welcomes a conversation with congressional Republicans about their competing vision, and that's why he's urged them to put forward their own budget, which is a necessary step to having that conversation.
- But I'd also note that the President has been clear about some things he won't agree to, including cutting Medicare benefits or taking away people's health care.
- The President looks forward to working with Congress to continue to strengthen Medicare's finances and reduce the cost of drugs for seniors.

Medicaid - Unwinding

TALKING POINTS:

- HHS has been working with all states for well over a year to prepare for the unwinding of the continuous enrollment condition, in order to ensure that as many people as possible maintain a source of coverage during this "unwinding" period.
- We are working closely with states to help ensure that people have continuity of coverage and established a Marketplace Special Enrollment Period from March 31, 2023 through July 31, 2024 for consumers who are no longer eligible for Medicaid or CHIP due to the end of the continuous enrollment condition.
- CMS also is helping states build on the progress made by continuous enrollment during the pandemic by implementing continuous coverage for kids nationwide. Thanks to the omnibus, beginning next year, children in Medicaid and CHIP will receive continuous enrollment for a full year.

QUESTIONS:

Q: What barriers have you seen that will prevent people from easily enrolling in their state? For example, I heard that South Carolina has paper-only re-enrollment and doesn't allow any electronic re-enrollment.

- CMS is working closely with states on their unwinding plans, including assessing state compliance with federal Medicaid redetermination requirements and, where necessary, developing mitigation strategies to address gaps/deficiencies.

Q: What are you doing to ensure that individuals are able to retain access to health coverage during unwinding?

- HHS has been collaborating closely with state agencies, other federal agencies, and stakeholders to plan and prepare for the end of the continuous enrollment condition through regular workgroups, all-state calls, and individualized technical assistance. These efforts are aimed at ensuring eligible enrollees retain coverage by renewing their Medicaid or CHIP coverage, and enrollees eligible for other sources of coverage smoothly transition.
- CMS has announced a Marketplace Special Enrollment Period (SEP) for qualified individuals and their families who lose Medicaid or CHIP coverage due to the end of the continuous enrollment condition. In October 2022, CMS also issued final rulemaking to establish a Medicare SEP to Coordinate with Termination of Medicaid Coverage, which allows individuals who have missed a Medicare enrollment period to enroll in Medicare after termination of Medicaid eligibility.

Q: How many people do you expect to lose Medicaid coverage this Spring and Summer?

- States will have up to 12 months to initiate, and 14 months to complete, a renewal for all individuals enrolled in Medicaid. CMS is working closely with states on their unwinding

plans, and CMS will be monitoring monthly data about activities related to eligibility determinations and redeterminations conducted during the unwinding period, including data related to terminations of coverage and transitions to other sources of coverage. CMS will be reviewing this data, state activity, and other information to ensure all states comply with federal requirements related to eligibility redeterminations and renewals, and is committed to providing additional information once available.

- o **IF PRESSED:** According to estimates from the Office of the Assistant Secretary for Planning and Evaluation, 15 million people could be disenrolled from Medicaid during this time period, and 8 million of those individuals will be eligible for other health coverage.

Q: HHS ASPE projects that 15 million individuals will lose Medicaid coverage, and other studies estimate 16 million. What is the difference between these projections and the projections in the Budget?

- CMS Actuaries project that 16.9 million individuals will lose Medicaid coverage in FY 2024 as a result of the ending continuous enrollment condition, and 19.5 million will lose coverage over the course of the unwinding period. Some reasons for the differences between the actuary projections and other studies include:
 - o CMS actuaries follow a timeframe of the fiscal year for purposes of the President's Budget
 - o CMS actuaries do not account for churning, beneficiaries going on and off of coverage, in their projections they develop for budget purposes
 - o CMS actuaries uses data from the Transformed Medicaid Statistical Information System (T-MSIS). Other studies may use different data sources with different metrics that could lead to variances in projections.

Q: Will the special enrollment period be available in all states, even the ones that don't rely on HealthCare.gov for their Marketplace?

- State-Based Marketplaces that operate their own eligibility and enrollment platforms can offer this SEP for their populations, and HHS encourages them to do so.

Q: Why aren't you requiring all states to offer the special enrollment period?

- State-Based Marketplaces that operate their own eligibility and enrollment platforms must determine whether to offer this SEP for their populations, and HHS encourages them to do so.

Q: Will Medicaid still be required to cover COVID-19 vaccines, testing, and treatment?

- If the COVID-19 PHE ends as expected on May 11, 2023, this COVID-19-specific coverage requirement will end on September 30, 2024. Under the American Rescue Plan Act of 2021 (ARP), states must provide COVID-19 vaccinations, testing, and treatments

under Medicaid and CHIP without cost sharing for through the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE.

- Even after the ARP provision expires, most people enrolled in Medicaid or CHIP will be guaranteed coverage of all approved vaccines, including COVID-19 vaccines, recommended by the Advisory Committee on Immunization Practices. That is because the Inflation Reduction Act closes gaps in vaccine coverage for adults in Medicaid and CHIP effective October 1, 2023. Medicaid and CHIP coverage of COVID-19 treatments and testing may vary by state.

Medicare Advantage

TALKING POINTS:

- Our vision for Medicare is for all seniors and people with disabilities to receive equitable, high quality, and person-centered care that is affordable and sustainable. This applies to beneficiaries in traditional Medicare and in Medicare Advantage.
- We recognize that Medicare Advantage is important for many beneficiaries. That's why we issued a Request for Information (RFI) last year seeking input on how to improve the MA program.
- Using this feedback, across multiple rules and the Advance Notice, we have proposed policies to strengthen beneficiary protections and enhance the MA program, including improvements that enhance payment accuracy.

QUESTIONS:

Medicare Advantage Advance Notice

Q: Is the MA Advance Notice actually a cut to Medicare and MA plan payments?

- Any claim that this Administration is cutting Medicare is categorically false.
- This Administration has proposed a roughly \$4 billion increase in MA payments for next year.

Q: What will the impact be on dually-eligible beneficiaries, lower-income enrollees, and racial or ethnic minorities?

- Bottom line, we are not proposing any policies that harm vulnerable beneficiaries.
- CMS is proposing essential updates to the risk adjustment model, including updates to reflect more recent cost and utilization data and to incorporate ICD-10 codes. These updates improve payment accuracy.
- We will continue to pay much more for someone who is dually eligible than someone who isn't even when they have the same diagnoses, and Federal law protects most dually eligible individuals from any cost sharing for Medicare services.
- The Medicare Advantage market is strong, and nothing in the Administration's proposed policies will change that.

Q: Will MA plans reduce the benefits they offer or increase premiums because of the Advance Notice?

- To be clear, on average, the Advance Notice would provide a payment increase for MA plans of 1.03%, or more than \$4 billion, next year.
- Also, all core Medicare benefits – such as hospital care and physician visits – are guaranteed in Medicare Advantage like they are in Traditional Medicare. These changes do not impact that requirement.

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- Looking at the past is helpful here. There have been years when the MA increase was smaller than what is proposed for 2024. We did not see premiums increase over those years. Instead, premiums remained relatively stable.
- MA is a highly competitive market where plans often compete for enrollees by keeping premiums down. In this competitive environment, we expect premiums to remain low.

Mental Health Parity

TALKING POINTS:

- The President's FY 2024 Budget includes numerous proposals to improve patient protections and strengthen enforcement of mental health parity requirements, including:
 - o Funding to states for parity enforcement;
 - o Eliminating Medicare's 190-day lifetime limit on psychiatric hospital services;
 - o Subjecting more plans – including Medicare Advantage plans – to parity laws; and
 - o Authorizing the Secretaries of HHS, Labor, and Treasury to regulate behavioral health network adequacy, and to issue regulations on a standard for parity in payment rates.
- The budget includes a proposal requiring Medicare and private insurance to cover up to three behavioral health visits per year with no cost-sharing. Eliminating cost-sharing for individuals removes potential financial barriers to treatment and gives more patients access to the care they need.
- The budget also includes a proposal to allow Medicare to identify and designate additional professionals to provide behavioral health care services, expanding access particularly in rural and underserved areas.

QUESTIONS:

Q: What does HHS do to enforce mental health parity requirements? Do you audit plans?

- HHS has primary enforcement authority over issuers in states that do not have authority to enforce or fail to substantially enforce the Mental Health Parity and Additional Equity Act (MHPAEA) (referred to as direct enforcement states) and non-Federal governmental health plans in all states.
- CMS is tasked with carrying out HHS's enforcement responsibilities.
- While CMS has some enforcement authority, states are the primary enforcers of mental health parity for health insurance issuers. The President's FY 2024 Budget includes a proposal that would grant states an additional \$125 million in funding for enforcement activities.

Q: Congress just added marriage and family therapist services to the Medicare statute, why are additional changes needed to Medicare?

- There are current statutory limits on the types of practitioners, and the scope of services, that are eligible for Medicare payment and these limits restrict access to behavioral health services.
- The Consolidated Appropriations Act of 2023 added coverage of marriage and family therapist services and mental health counselor services under Part B of the Medicare program starting January 1, 2024.
- However, other providers including peer support workers and certified addiction counselors are still unable to bill Medicare directly.
- The Budget proposes to allow Medicare to identify and designate additional professionals who can enroll in Medicare and be paid when furnishing behavioral health services within their

applicable state licensure or scope of practice that would otherwise be covered when furnished by a physician.

- The proposal also:
 - o Removes limits on the scope of services for which Clinical Social Workers can be paid by Medicare.
 - o Establishes a Medicare benefit category for these professionals that authorizes direct billing and payment under Medicare for these practitioners;
 - o Removes limits on the scope of services for which they can be paid by Medicare;
 - o Allows these practitioners to bill Medicare directly for their mental health services for covered Part A qualifying Skilled Nursing Facility stays;
 - o Establishes Medicare payment under Part B for services provided under an Assertive Community Treatment delivery system which provides treatment for the severe functional impairments associated with serious mental illness;
 - o Allows payment to Rural Health Clinics and Federally Qualified Health Centers for these additional behavioral health professionals providing mental health services; and
 - o Enables Medicare coverage of evidence-based digital applications and platforms that facilitate the delivery of mental health services.

Mental Health – Youth

TALKING POINTS:

- Children and young people in this country are facing an unprecedented behavioral health crisis
- Diagnosis of anxiety, depression, and other mental health conditions, as well as the rate of youth overdose deaths continue to rise at alarming rates.
- Improving mental health and wellness for everyone -- particularly for children and young people—and addressing the challenges that have been exacerbated by the COVID-19 pandemic is a top priority for HHS.

QUESTIONS:

Q: How has the COVID-19 pandemic and mask wearing impacted children's mental health and what is HHS doing about it?

- Data show that for across a broad range of social, emotional, and cognitive outcomes, allowing kids to attend school in person is incredibly important.
- Accordingly, the Biden Administration has prioritized in-person schooling in its COVID response plan.
- HHS is responding to the current crisis by developing and expanding grant programs that address the mental health needs of our children and youth, including school-based programs and community-based trauma-informed services for children and youth, and their families that meet children and families where they are.

Q: A few months ago, HHS/SAMHSA released the results of its annual National Survey on Drug Use and Health. In 2021 amount people 12 and older, 61.2 million people, 21.9 percent of the US population, used illicit drugs this past year. 3.7 million, 14.1 percent of 12- to 17-year-olds have used illicit drug. These are children and substance use among America's kids only seem be increasing. Why should we continue providing SAMHSA additional dollars when it is clear what you are doing is not making a positive impact?

There is no question that more needs to be done, and with support from Congress we are taking action, expanding grant programs that address the mental health needs of our children and youth, including school-based programs and community-based trauma-informed services for children and youth, and their families that meet children and families where they are.

If pressed on the specifics of the data and year-over-year increase:

- To clarify, estimates from the 2021 National Survey on Drug Use and Health should not be compared with estimates from previous years because the COVID-19 pandemic necessitated methodological changes to the data collection process.

- HHS is committed to providing access to prevention and treatment services to everyone, include youth and young adults, and a commitment to data and evidence is one of SAMHSA's four core principles.
- The National Survey on Drug Use and Health is a vital data tool that supports SAMHSA's mission and aligns with SAMHSA's vision to guide stakeholders in developing policies and programs to help people in the United States who have, are affected by, or are at risk for mental health or substance use conditions receive care, thrive, and achieve wellbeing.

Q: Please give an example of how HHS agencies are coordinating to address youth mental health and substance use disorder conditions?

- When I was confirmed, I immediately established the Behavioral Health Coordinating Council (BHCC)—all HHS agencies participate and lead committees across five key areas: data and evaluation, youth, crisis and suicide, overdose prevention, and integration. Committees all consider equity and workforce as part of their charge.
- SAMHSA and CMS lead our BHCC youth group together. And they also work together through the Interdepartmental Serious Mental Illness Coordinating Committee, which was established to make recommendations for actions that federal departments can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance, has parity implementation as a goal.

Mifepristone

TALKING POINTS:

- [ON HOLD UNTIL DECISION]
- Holding Statement if Decision Comes out During Hearing:
 - “This is chilling news for America and will have dire consequences for women across the country. The Biden-Harris Administration is resolute in our commitment to protect access to abortion care – we are looking closely at the decision and are examining our options.”

QUESTIONS:

Q: Does HHS have any workarounds to this decision?

- [ON HOLD UNTIL DECISION]

Q: What do providers/patients do with existing mifepristone?

- [ON HOLD UNTIL DECISION]

Q: If you feel that this decision was made erroneously, why don't you just defy the ruling?

- [ON HOLD UNTIL DECISION]

Q: Are you going to issue a Public Health Emergency to increase access to reproductive health care?

- We have always said we would not take any option off the table that will help expand access to reproductive care.
- But, at this point in time, we do not believe that declaring a public health emergency would provide meaningful new resources in this fight.

Nonrecurring Expenses Fund

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Notification	525	650	125
Rescission	(650)	(350)	300

TALKING POINTS:

- HHS relies on modern information technology and safe and functional facilities to meet its mission to enhance the health and well-being of Americans.
- The Nonrecurring Expenses Fund enables HHS to address high-priority capital investments that simply do not get funded in the annual appropriations process.
- Every dollar rescinded from the fund comes at the expense of keeping departmental systems and facilities in good working order.
- Approximately two-thirds of HHS' NEF-eligible needs are not even proposed to Congress due to these rescissions and allocations.

QUESTIONS:

Q: How much of the NEF has funded Capital Expenditures?

By statute all NEF investments must be capital expenditures necessary to operate the Department. Since its inception, HHS has obligated \$1.9 billion in facilities and \$2.7 billion in IT capital expenditures previously notified to Congress. HHS is currently in the process of spending the remaining \$1.3 billion in notified funds.

Nursing Homes - Staffing Ratios

TALKING POINTS:

- One of the key areas of focus in President Biden's nursing home quality initiative is nursing home staffing.
- The COVID-19 pandemic highlighted and exacerbated the long-standing staffing challenges experienced in many facilities, creating an urgent need to address this issue for the well-being of all individuals residing in our nation's federally certified nursing homes, and the workers who care for them.
- HHS has launched a multi-faceted approach aimed at determining the minimum level and type of staffing needed to enable safe and quality care in nursing homes. As part of this effort:
 - o CMS is currently in the process of conducting a mixed methods study
 - o CMS will release a proposal in spring 2023 for minimum staffing levels in nursing homes.

QUESTIONS:

Q: How has the nationwide health care workforce shortage impacted rural providers that are already struggling?

- We know that providers across the country are still facing challenges introduced or exacerbated by the COVID-19 pandemic, including workforce shortages, and these challenges can be particularly difficult for providers in rural areas.
- Health care should be accessible, no matter where you live, and the Biden-Harris Administration is dedicated to improving access to health care in rural communities and addressing the issues which contribute to health inequities impacting these communities.

Q: Will your nurse staffing proposal include an exception or other flexibilities for rural nursing homes?

We are aware of the unique challenges facing rural nursing homes and we are taking those challenges into account as we develop the proposal. We look forward to robust comment from the rural community on the proposal when it is released.

Q: The health care workforce shortage is reaching a crisis, yet the Administration still refuses to let healthy, qualified professionals work unless they've received an experimental vaccine that doesn't even prevent COVID-19. Now that the Public Health Emergency is coming to an end, don't you think it's time to get rid of the vaccine mandate as well?

- We know that the COVID-19 vaccine saves lives, and the Biden-Harris Administration has made it a priority to continually work to reach, vaccinate, and protect our most vulnerable communities across the country.
- Hospitalizations and deaths from COVID-19 currently remain relatively low nationwide. This is a testament to the tools and protections put in place by this Administration, including efforts to educate consumers and expand access to the vaccine.
- HHS is committed to taking critical steps to protect vulnerable individuals and ensure America's health care facilities are prepared to respond to public health emergencies.

Ohio Train Derailment

TALKING POINTS:

- HHS stands with the people and communities impacted back the train derailment in Norfolk Southern. Multiple parts of HHS are part of the federal response.
- In February, CDC/ATSDR sent a team of 23 staff to conduct an Assessment of Chemical Exposures (ACE) investigation, including door-to-door recruitment of affected residents.
- As of March 7, 2023, over 420 residents and 190 first responders have participated in the ACE survey.
 - The investigation is providing information to inform the states' public health response, assess the need to modify emergency response procedures, focus outreach efforts, and identify groups of exposed people that may need additional follow-up.
- The Health Resources and Services Administration (HRSA) has provided an emergency grant to the Community Action Agency of Columbiana County (CAAC). HRSA approved, \$250,000 in emergency funding. This funding will support key response activities, including direct health care services, patient screenings, and outreach and enrollment.
- HHS will continue to support the community throughout the next stages of the response whether that's through reviewing environmental sampling data to assess public health impact or to provide mental health support, we stand ready to assist.

QUESTIONS:

Q: Some residents and experts have stated a need for testing to measure the level of chemicals the residents and responders to the East Palestine incident were exposed to. Why hasn't CDC/ATSDR offered biomonitoring or other testing to residents?

- I understand that many residents and responders have concerns regarding the longer-term health outcomes resulting from the train derailment. HHS is committed to supporting the residents of East Palestine and the surrounding communities to address their concerns, including answering their questions about how testing may help them protect their health.
- At this time, CDC and ATSDR are not recommending specialized testing for the levels of chemicals in people's bodies, as tests for the chemicals involved in this event do not usually provide information to help doctors manage health problems or disease.
- We are supporting state efforts to connect concerned residents with medical providers to ensure they have access to follow-up care in the long-term to address any individual health issues that may arise.
- CDC and ATSDR are also working with partners to provide information to health care providers about additional steps they can take in consultation with their patients, including other routine blood and urine tests that they can take to protect their patients' health.

Q: When will you have ACE results? Will there be one report? Who will release the report/findings and how long will this take?

- The resident and responder surveys for the Assessment of Chemical Exposures, or ACE, investigation will be open through the end of the month, and data analysis is ongoing. Over the next several months, CDC and ATSDR will work together with the health departments to analyze data and share results.
- These results will provide information about appropriate next steps to address potential health impacts of exposures.
- This is a collaborative, iterative process and CDC/ATSDR will continue to work closely with the health departments as the analyses are completed and results are shared.

Q: Does the CDC recommend that we study these people over time to learn about the health effects?

- The health of the residents and the community overall is very important to us. I know that community members are concerned about their health and understand how unsettling it can be not to know what these exposures mean.
- We hope to learn more from the ACE survey in the community and among responders to give us more information to address the health concerns of the residents.
- We will analyze the data with our colleagues from the Ohio and Pennsylvania health departments and come up with a plan for next steps. This may include long-term health monitoring, additional epidemiologic support, or suggest research studies to fill knowledge gaps.

Q: How does ATSDR produce their screening levels for exposures (also called comparison values). How are these values used and why are these values different than the ones the EPA and health departments are using?

- ATSDR has been on the ground supporting the EPA and local officials in their response to the derailment for over a month. At the request of the EPA and state health departments, ATSDR provided comparison values to the EPA and state health departments for consideration in their risk management process.
- We defer to EPA and the state health departments for more information on how these comparison values are used in the risk management process.
- Determining the threshold for unsafe levels of chemical exposure is a complex process given there are many site-specific factors that need to be considered. ATSDR derives non-regulatory comparison values as screening values to help public health professionals determine which exposures may need further evaluation. ATSDR uses the lowest comparison value available to protect public health for a specific incident.

- Concentrations below these values are unlikely to cause harmful health effects. Exposures above these values do not necessarily mean that harmful effects will occur but serve as a signal for public health professionals to look more closely.

Older Americans Act

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Protection of Vulnerable Older Adults	96	144	+49
Health and Independence for Older Adults	1,587	1,939	+352
Caregiver Services	259	311	+49
Total Program Level	2,650	3,142	+493

TALKING POINTS:

- At some point in our lives, nearly all of us will need assistance with things like transportation, personal care, and managing finances, or provide assistance to someone else we care about. Strengthening and supporting the caregiving infrastructure is a top priority for this Department.
- ACL's budget request includes an increase of nearly \$66 million to support:
 - a range of services to support family caregivers including respite care,
 - efforts to implement recommendations from the National Strategy to Support Family Caregivers, and
 - demonstration grants and a technical assistance center to expand and stabilize the direct care workforce.
- The demand for services provided through the ACL's programs has risen sharply in recent years and continues to grow. Expanding access to these direct services is a priority.

QUESTIONS:

Q: Falls among older adults result in \$50 billion in medical costs annually – \$38B in Medicare and Medicaid; and \$12B in private insurance or out-of-pocket expenditures. What are you proposing to improve this situation?

- First, I wanted to thank Congress for your support of HHS falls prevention work. In particular, the \$5 million that was appropriated in FY 2023 for the Administration for Community Living's Research, Demonstration and Evaluation Center. Those funds are supporting continued research in the causes and associated illnesses that can lead to falls as well as interventions effective in preventing falls.
- As part of ACL's investment in direct services, we are requesting an additional \$2 million within our promoting healthy aging efforts to expand the successful evidence-

based falls prevention program in the community and educate more older Americans about ways to reduce their falls risk.

Q: You have indicated that direct services for older adults and people with disabilities are a priority and nutrition services in particular. Why are you proposing to cut the Nutrition Services Incentive Program by \$48 million?

- I agree, funding to meet nutrition needs – whether at group dining sites like senior centers or through home-delivered meals – are critical to enabling seniors to remain in their communities and to age in place. The Nutrition Services Incentive Program is a secondary source of funding for the nutrition services.
- We have requested an overall increase to these programs through their primary funding, which comes to \$217.6 million over the FY 2023 budget. We believe increasing primary funding will have the most direct impact on addressing the nutrition needs of seniors.

Q: What does this budget do to address elder abuse and neglect?

- Abuse and neglect rob people of their fundamental human rights and erode their opportunity to participate as members of the community. We are in a national crisis – abuse of older adults increased nearly 84 percent during COVID.
- I thank Congress for providing the first federal funding for APS formula grants in FY 2021 and I am so pleased that ACL received ongoing funding to support Adult Protective Services in FY 2023.
- Our request for FY 2024 is to get to a basic level of funding to continue to protect older adults and adults with disabilities from abuse and neglect.

Organ Transplantation

(Dollars in Millions)

	FY 2023	FY 2024	
	Enacted	President's Budget	+/- FY 2023 Enacted
Organ Transplantation	31,049	67,049	+36,000

TALKING POINTS:

- We are committed to increasing the number of registered organ donors and initiatives to remove financial barriers to living organ donation and to ensure that donor allocation is done in a transparent and equitable manner.
- As you know, almost 40 years ago, Congress established the Organ Procurement and Transplantation Network (OPTN) to coordinate and operate the nation's organ procurement, allocation, and transplantation system.
- We are currently engaged in efforts to modernize the OPTN to further strengthen accessibility, equity, transparency, and system performance.
- We want to work with Congress to continue our efforts to improve organ transplantation. The President's Budget includes a proposal for the resources and authorities needed to oversee the operational activities, performance, and accountability of the OPTN.

QUESTIONS:

Q: How is HHS providing oversight to ensure accountability and equity of the Organ Transplantation and Procurement Network system?

- The Budget provides an additional \$37 million to increase accessibility, transparency, and equitable distribution of organs through modernization of the Organ Procurement and Transplantation Network.
- Specifically, the request will support efforts to:
 - strengthen policy, governance, and technology to drive improvements in IT system performance, health equity, patient outcomes and patient safety
 - launch implementation of the design features needed to improve system processes, patient experience, and accountability

Oversight

TALKING POINTS:

- HHS is committed to working in good faith to address congressional oversight requests in a timely manner.
- Already this Congress, HHS has made significant document productions in response to multiple committees' oversight inquiries, and I know we are actively working to continue addressing Congress's oversight requests.
- We look forward to working together and continuing our productive relationships with Congress.

QUESTIONS:

Q: Will you provide complete responses to my oversight requests by the deadline requested?

- We are committed to engaging in good-faith negotiations to meet the informational needs of Congress while protecting the institutional interests of the executive branch.
- We will continue to engage in this process to address congressional oversight requests, like we always have.
- *If pressed on commitments:* I know our staff is working hard to address the significant number of oversight requests that we have received this Congress. We look forward to continuing those discussions.

Q: Is it your policy that Committee Chairs must send new oversight letters this Congress to get answers to letters we sent in the last Congress?

- It is my understanding that, when a new Congress begins, there is a long-standing practice across Departments for oversight requests to be sent by the new Chairs, once they have been selected.
- This helps ensure we are prioritizing oversight requests from current committee Chairs.
- The Department welcomes current Chairs to send oversight letters identifying their priorities for this Congress and stands ready to work in good faith to address these requests.

Pandemic Preparedness

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA	153.113	181.880	+28.767
CDC ¹	1,654.300	2,037.400	+383.100
NIH ²	2,943.000	2,944.000	+1.000
ACF	1.864	8.000	+6.136
ASPR ³	3,629.677	4,271.913	+642.236
PHSSEF ³	115.992	278.318	+162.326
Pandemic Preparedness Initiative	--	20,000	+20,000
Total Program Level	8,497.946	29,721.511	+21,223.565

1/ FY 2023 totals are comparably adjusted to reflect funds for HHS Protect within CDC's Center for Preparedness and Response. The FY 2023 enacted located HHS Protect Funding within PHSSEF, but the program is implemented by CDC.

2/ NIH estimates for FY 2023 and FY 2024 align to the NIH Biodefense category.

3/ The Public Health and Social Services Fund previously contained the annual appropriation for the Administration for Strategic Preparedness and Response (ASPR). The FY 2024 budget requests funding for ASPR in a separate, new appropriation account. This table is comparably adjusted to break out ASPR from the PHSSEF.

TALKING POINTS:

- Strengthening our nation's preparedness for public health threats of all sources is a national security imperative and a top priority for this Administration.
 - HHS has had to overcome real administrative challenges and a patchwork of authorities and flexibilities while responding to the once-in-a-century COVID-19 pandemic and other recent emergencies, including the infant formula shortage and Hurricanes Ian and Fiona.
- This work is **mission-critical** for HHS, we must better respond to future outbreaks, strengthen domestic production capabilities and anticipate and prevent their worst public health and economic harms.
- We propose a suite of funding and legislative proposals to strengthen capabilities across early threat detection, supplies and medical countermeasures, workforce, recovery, and core infrastructure and capabilities.
- This includes discretionary investments and \$20 billion in mandatory funding requested across HHS public health agencies to prepare for pandemics and other biological threats. Together, these proposals will help bridge key gaps and barriers to enable a robust and timely response to future emergencies.
- I stand ready and eager to discuss the path forward with Congress.

QUESTIONS:

Q: Last Congress, we passed the PREVENT Pandemics Act, didn't that get HHS the authorities it needs to better respond to emerging public health threats?

- First, I want to thank Congress for working on bipartisan basis to support HHS work on pandemic prevention.
- PREVENTs took us one step forward, but the proposal in the FY2024 budget and Congress' work to reauthorize the Pandemic All-Hazards and Prevention Act (PAHPA) will provide enduring ability for the department to leverage the processes we know worked from COVID-19, like DOD's contracting authority for rapid research, and development and procurement of vaccines and medical countermeasures. HHS will be able to leverage to prepare and respond to future public health threats.

Q: Right now, the Centers for Disease Control and Prevention (CDC) do not have an explicit authorization. Do you think Congress should authorize the CDC and if so what should it look like?

- CDC launched Moving Forward to strengthen CDC by strategically building on lessons learned during the COVID-19 pandemic to break down silos, reduce bureaucracy, and improve accountability.
- This effort will be critical to deliver health information more clearly and quickly to policy makers and American. We're already seeing the benefits of this effort:
 - CDC was the first in the world to produce data showing real-world effectiveness of the JYNNEOS vaccine for mpox.
 - Two public-facing databases went live in April 2022 that provide public health practitioners and the public with critical data about non-fatal overdoses and overdose deaths to tailor interventions in their communities.
- As CDC makes the changes it can internally, we also need help from Congress through funding and new authority to fully deliver on its mission of protecting the health, safety, and security of Americans.

Q: Why is the Pandemic Preparedness Mandatory Proposal \$20 billion less? If this is mission critical why are you proposing less funding to achieve the same goals?

- The Administration remains committed to transforming the way we prepare for and respond to pandemic and other biological threats. That's why we are again asking Congress to enact bold legislation.
- The \$20 billion proposal in the FY 2024 budget is a targeted investment. While it cannot do everything, it will allow for significant progress toward meeting the Administration's preparedness goals, as outlined in the National Biodefense Strategy and Implementation Plan and American Pandemic Preparedness plan.

Q: U.S. intelligence assessments point to the possibility that SARS-CoV-2 originated from a leak at the Wuhan Institute of Virology (WIV). Did HHS/NIH fund work at WIV that resulted in the pandemic?

- NO. NIH has never approved any research that would make a coronavirus more dangerous to humans. The body of science reported—including the bat coronavirus

sequences published in the scientific literature—showed that the viruses studied at WIV under the NIH grant were evolutionarily quite distant from SARS-CoV-2 and could not have been the source of SARS-CoV-2.

- The origin of SARS-CoV-2 virus has not been identified, despite intensive efforts. It took 14 years for scientists to find a single bat population that contained all the necessary genetic components of SARS-CoV, the virus that caused the 2003 SARS epidemic. We still do not know the origins of the 2014 Ebola outbreak.
- HHS strongly supports efforts to identify the SARS-CoV-2 origin.

Q: What is HHS/NIH doing to ensure biosafety and biosecurity of research involving pandemic pathogens?

- HHS/NIH is committed to ensuring the safety and security of the work we support. The U.S. has a robust biosafety and biosecurity oversight system that is predicated on identifying and assessing benefits and risks, and appropriately mitigating risks at both the Federal and institutional levels. We periodically review, and as needed, update our oversight frameworks to help ensure our biosecurity oversight frameworks keep pace with rapid advances in science.
- In February 2022, HHS tasked the National Science Advisory Board for Biosecurity (NSABB), a federal advisory committee, with reviewing the scope and effectiveness of two major U.S. biosecurity policy frameworks governing research with enhanced potential pandemic pathogens and dual use research of concern.
- The NSABB's final report was delivered in March 2023. NSABB findings and recommendations will inform ongoing USG policy deliberations.

Q: Did the NSABB consider the origins of the SARS-CoV-2 pandemic and NIH's funding of research in China?

- No, investigating the pandemic's origin was not the role of the NSABB and many other investigative bodies have been tasked with this charge.

Q: Given the potential risks, why does HHS/NIH support research involving potential pandemic pathogens?

- Research involving potential pandemic pathogens can help us understand the fundamental nature of human-pathogen interactions, assess the pandemic potential of emerging infectious agents such as viruses, and inform public health and preparedness efforts, including surveillance and the development of vaccines and medical countermeasures.
- While such research is inherently risky and requires strict oversight, the risk of not doing this type of research and not being prepared for the next pandemic is also high.

Q: Why does HHS/NIH support pathogen research in foreign countries?

- HHS/NIH supports research to better understand the characteristics of animal viruses that have the potential to spill over to humans and cause widespread disease. We must collaborate with researchers in other countries where these viruses are prevalent because once a virus spreads to humans, it is not contained by geographical boundaries. Our support ensures that the information will be shared.
- This has helped us to assess the pandemic potential of emerging infectious pathogens, including coronaviruses that have caused SARS and MERS. This is our best path to inform the development of medical countermeasures such as vaccines. It would be irresponsible for us not to do this work.
- In fact, this body of work has helped make it possible for the U.S. government to move so quickly to get a COVID-19 vaccine in an unprecedented timeframe of just 11 months. Countless lives have been saved as a result.

Public Health Emergency - Uninsured Program

TALKING POINTS:

- The Biden-Harris Administration is committed to ensuring continued access to COVID-19 vaccines and treatments for all Americans.
- Congress established funding for the Uninsured Program to provide claims reimbursement to health care providers for during the COVID-19 pandemic testing, treatment and vaccinations administration for uninsured individuals.
- As of March 1, 2023, HHS has made **\$24.5 billion in claims reimbursement payments** to providers for testing, treatment, and vaccination of uninsured individuals. Including:
 - Over 11.3 billion claims for testing;
 - 5.8 billion claims for treatment; and
 - 1.6 billion claims for vaccine administration.
- HHS has processed and paid nearly all eligible claims submitted to the program by the deadlines. There are a small number of claims remaining requiring technical, administrative adjustments or program integrity review.
- Due to a lack of sufficient funding, in March 2022, HHS announced that the COVID-19 Uninsured Program would have to stop accepting claims. To date, no additional funding has been appropriated for the Uninsured Program.

QUESTIONS:

Q: How much has been spent on the Uninsured Program?

- As of March 1, 2023, HHS has made \$24.5 billion in claims reimbursement payments to providers for testing, treatment, and vaccination of uninsured individuals.

Q: How much is money is left in the Uninsured Program?

- On March 15, 2022, the White House announced that the COVID-19 Uninsured Program would have to stop accepting claims for testing and treatment on March 22, 2022, and stop accepting claims for vaccination administration on April 5, 2022, due to a lack of sufficient funding.
- To date, no additional funding has been appropriated for the Uninsured Program, and claims are no longer being accepted.

Q: Is HHS still processing claims in the Uninsured Program?

- HHS has processed and paid nearly all eligible claims submitted to the program by the deadlines. There are a small number of claims remaining requiring technical, administrative adjustments or program integrity review.

Q: How did HHS prevent fraud or abuse in the Uninsured Program?

- HHS implemented numerous program integrity and fraud prevention measures as part of the Uninsured Program. To participate in the Uninsured Program, providers were required to undergo multiple verification steps, including submitting their *National Provider Identifier* (NPI) and their Tax Identification Number for validation. Providers also were checked against several provider compliance and exclusion lists to assess whether they are in good standing.
- Specifically, HHS excludes providers who:
 - o Were excluded from participation in Medicare, Medicaid, or other Federal health care programs;
 - o Were on the List of Excluded Individuals/Entities from HHS's Office of the Inspector General; or
 - o Were terminated from participation in Medicare or precluded from receiving payment through Medicare Advantage or Medicare Part D; or
 - o Had their Medicare billing privileges revoked.
- Providers who are suspected to be or found to be out of compliance with the terms and conditions of the Uninsured Program can be subject to holds on reimbursements, post-payment reviews, termination from the program, recovery of funds, and referral to law enforcement as appropriate.

Public Health Emergency and Telehealth (not controlled substances)

TALKING POINTS:

- **PHE END BUDGET:**

- **Medicaid**

- In FY 2024, the federal government will spend an estimated \$556.2 billion on the Medicaid program, a decrease of \$51.5 billion below 2023. This decrease in spending is due to the end of the continuous enrollment condition in Medicaid on March 31, 2023.
 - CMS continues to work with states on their Medicaid and CHIP renewal plans and system readiness as the continuous enrollment condition comes to an end on March 1, 2023. CMS also focuses on continuity of coverage and streamlining transition to alternate forms of coverage for beneficiaries by launching two outreach and information campaigns targeted towards beneficiaries, and announcing a marketplace special enrollment period for individuals who lose Medicaid coverage during the unwinding period.

- **Private Insurance**

- The FY 2024 budget includes \$281 million for Marketplace consumer information and outreach and \$141 million for Navigators. This includes paid media and direct consumer enrollment assistance, which will support the transition of eligible Medicaid recipients to Marketplace coverage.

- **Discretionary**

- Digital Healthcare Research: +\$2 million above FY 2023 enacted, for a total of \$18 million for AHRQ's Digital Healthcare Research Program. Increases will be used to establish Centers of Excellence in Telehealth Implementation that will generate essential new evidence to understand telehealth's effect on access, equity, and quality and inform key policy decisions to maximize telehealth's impact.

- **TELEHEALTH:**

- **Medicare**

- Most of the current Medicare telehealth flexibilities that Medicare beneficiaries have relied on over the past two years will remain in place through December 2024 due to the Consolidated Appropriations Act, 2023 passed by Congress in December 2022, such as:
 - Access to telehealth services in any geographic area in the United States, rather than only those in rural areas.
 - Receive in-home telehealth visits that Medicare pays for rather than traveling to a health care facility.
 - Cover certain telehealth visits delivered audio-only (such as a telephone) if someone is unable to use both audio and video, such as a smartphone or computer.
 - Medicare Advantage plans may offer additional telehealth benefits.

- Additionally, after December 31, 2024 when these flexibilities expire, some Accountable Care Organizations may offer telehealth services that allow primary care doctors to care for patients without an in-person visit, no matter where they live.
- **Medicaid**
 - States have significant flexibility with respect to covering and paying for Medicaid services delivered via telehealth. State requirements for approved state plan amendments vary as outlined in CMS' Medicaid & CHIP Telehealth Toolkit. This flexibility was available prior to the COVID-19 PHE and will continue to be available after the PHE ends. Like Medicare, these telehealth flexibilities provide a vital lifeline to many individuals receiving Medicaid, particularly for persons in rural areas and those with limited mobility.
- **Private Insurance**
 - During the PHE, high deductible health plans were granted a temporary safe harbor to cover telehealth and remote care services on a first dollar basis without jeopardizing Health Savings Account contributions. This safe harbor has been extended through December 31, 2024 due to the Consolidated Appropriations Act, 2023.

Questions:

Q: How will the transition from the public health emergency affect Medicaid Telehealth? budget?

A: Under Medicaid statute, telehealth is a mode of delivery, not a separate services. States have flexibility to continue pandemic changes they may have made under current law.

Q: Why does the HHS budget not permanently extend telehealth flexibilities in Medicare?

A: HHS is committed to supporting a temporary extension of some broader telehealth coverage flexibilities under Medicare beyond the COVID-19 Public Health Emergency. However, we also support Congressional mandates to study whether Medicare's telehealth flexibilities promote proper use and access to care. Additionally, HHS continues to work closely with Congress to provide technical assistance on several introduced telehealth bills and others that are in development. We urge Congress to extend permanently several high priority Medicare telehealth provisions:

- (1) Coverage of services with the patient's home as an originating site;
- (2) Federally Qualified Health Centers and Rural Health Clinics provisions allowing both to serve as distant sites;
- (3) Payment parity for behavioral telehealth services, based on strong evidence that telehealth is as effective as standard in-person treatment in this area; and
- (4) Audio-only access for patients whose circumstances necessitate that as the preferred mode of care delivery (whether due to broadband limitations, lack of video-enabled devices, data limitations, and/or beneficiary preference).

Q: What telehealth flexibilities remain in Medicaid after the PHE ends?

A: States generally have broad flexibility to cover and pay for services provided via telehealth in their Medicaid program. States may apply to CMS for waivers or state plan amendments to continue telehealth flexibilities that expire as a result of the end of the PHE.

Q: What telehealth flexibilities remain in Marketplace plans after the PHE ends?

A: As is currently the case during the PHE, coverage for telehealth and other remote care services will vary by private insurance plan after the end of the PHE. When covered, private insurance may impose cost-sharing, prior authorization, or other forms of medical management on telehealth and other remote care services.

Public Health Emergency - Unwinding

TALKING POINTS:

- While COVID is not over, because of the Biden Administration's whole of government response since day 1, we distributed over **965 million vaccines**, and now we are in a position where we can effectively lift the Public Health Emergency (PHE) and the National Emergency.
- The Administration will now execute the process of a smooth **operational wind down** of those emergency policies enabled by the COVID-19 emergency declarations, including waivers that give healthcare providers and systems the flexibilities needed for operations and staffing to provide expanded and continued access to high quality of care.
- We will continue to communicate to States, health care providers, and the public in the coming days and months, what that process means and working with states and jurisdictions to ensure an orderly transition.

QUESTIONS:

Q: How will this impact the uninsured?

- This decision to unwind the PHE and lift the National Emergency is distinct from our longer-term planning on the transition of vaccines and additional therapeutics to the commercial market.
- Right now, COVID-19 vaccines and certain therapeutics remain free and widely available. We will be transitioning to commercial markets later this year, but making sure that the uninsured have continued access to vaccines and treatments is one of the Administration's highest priorities.

Q: What about 1135 waivers? What about telehealth?

- CMS has been working with stakeholders over the last few months to understand the flexibilities enabled by these 1135 waivers and other mechanisms and plan for their eventual end.
- Last August, CMS developed a roadmap for the eventual end of the waivers and flexibilities, and shared information on what health care facilities and providers can do to prepare for future events.
- Similar to the guidance CMS has made available to states, CMS released fact sheets that will help the health care sector transition to standard operations once the PHE ends.
- Regarding telehealth, certain major flexibilities in Medicare coverage for certain telehealth services will remain in effect through at least December 31, 2024.
- However, ending the PHE would terminate flexibilities in the prescribing of certain controlled substances via telehealth. The Drug Enforcement Administration Has proposed

rulemaking in this area, and we look forward to working with our DOJ colleagues and stakeholders on a final rule.

Q: What data powers does this relinquish?

- The PHE has facilitated our monitoring of variants by allowing the Centers for Disease Control and Prevention (CDC) to impose requirements for data reporting.
- CDC has been working with jurisdictions to continue to voluntarily provide data; the wind down will give CDC the time that it needs to continue to negotiate agreements with all jurisdictions.

Q: What is the timeline for commercialization of the COVID-19 vaccines and treatments?

- While there are many considerations and timelines may shift based on the trajectory of the virus, we anticipate that the transition of vaccines to more traditional pathways for procurement, distribution, and payment will occur in early fall.
- Some of those considerations include what will be authorized and recommended by FDA and CDC, and what will align with a strain change for potential variants.
- Provided that one is authorized and recommended by FDA and CDC, we expect this transition will align with a possible strain change that accounts for any potential variants.
- The treatments transition to commercial markets will vary by product and will likely occur for at least one product before the end of the year.
- The USG is working on determining the exact dates for COVID-19 vaccines and therapeutics. We will share more information about timelines when we are able.

Q. What is the impact of the end of the COVID-19 Public Health Emergency (PHE) on May 11 on access and costs to COVID-19 vaccines and treatments?

- The PHE does not affect the transition of vaccines and treatments to commercial markets.
- In February 2023, HHS Secretary Becerra renewed the PHE for one last 90-day period planned to end at the end of the day on May 11, 2023. This action is based on the most recent COVID-19 trends and is consistent with the Administration statement on January 30, 2023, that the PHE is planned to end at the end of the day on May 11.
- In the past, HHS has committed to providing 60 days-notice in advance of ending the PHE. To foster a smooth transition, HHS has given 90 days-notice instead.
- Even with the planned end of the PHE at the end of the day on May 11, on May 12, all vaccines and treatments purchased by the U.S. government will continue to be distributed and available for free to U.S. residents. The PHE itself does not affect the supply or

distribution of our vaccines or treatments. It also does not affect FDA's ability to authorize various products, including tests, treatments, or vaccines for emergency use.

Q. How will commercialization change the accessibility of COVID-19 vaccines and treatments?

- COVID-19 remains a significant public health priority for the Administration and for HHS. We know so many are still affected by COVID-19, particularly seniors and people with disabilities. We remain committed to maximizing availability of COVID-19 vaccines and treatments.
- Our intention is that vaccines and treatments will remain available from all of the places U.S. residents currently receive them, whether it's at their pharmacy or their health care provider.
- Vaccines will remain free for most U.S. residents through the Vaccines for Children Program, Children's Health Insurance Program, most commercial insurance, Medicare, and Medicaid programs.
- Those with Medicare, Medicaid, and most private insurance will be able to access covered treatments, potentially with cost-sharing.

Q. How will Vaccines be available for the un- and under-insured?

- CDC's Vaccines for Children Program will provide coverage for uninsured children as it does for other routine vaccinations.
- HHS is actively working with vaccine and treatment manufacturers to ensure that Patient Assistance Programs that provide free access to these products are easy to use and broadly accessible.
- HHS continues to invest in health systems and programs that support vaccine access and outreach in underserved communities – such as Federally Qualified Health Centers, Rural Health Clinics, and state and local health departments. These networks can be leveraged for access to COVID-19 vaccines and therapeutics as well as other needed medicines.

Physician Payments

TALKING POINTS:

- HHS values the critical role that physicians and other health care professionals play in health care delivery.
- Ensuring adequate Medicare payments for providers is essential to maintain beneficiary access to high-quality and affordable health care.
- I appreciate Congress' leadership in the Consolidated Appropriations Act, 2023 to (1) provide a temporary, one-year increases payment amounts for all services under the physician fee schedule by 2.5 percent in 2023 and 1.25 percent in 2024 and (2) extend incentive payments for clinicians who are qualifying participants in advanced alternative payment models for one year through 2025, though at a lower rate (3.5 percent rather than 5 percent).

QUESTIONS:

Q: Medicare cuts in physician payments are driving health system consolidation, exacerbating provider shortages and access issues, and hurting our health system's responsiveness and capabilities for future pandemics. Why did CMS cut physician payments again for 2023?

- The Biden-Harris Administration is committed to protecting and strengthening Medicare so that Americans of every generation can count on it and ensuring that providers receive appropriate payments is a critical part of our efforts.
- HHS is required to base payments for services under the physician fee schedule on the relative resource costs involved in furnishing a service, and the fee schedule is subject to statutory budget-neutrality requirements.
- HHS does not have the legal authority to implement increases in payment outside of budget neutrality without additional action taken by Congress.

PrEP Delivery Program to end HIV Epidemic

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
PrEP Delivery Program Cost	-	237	+237
Total Program Level	-	237	+237

Note: The FDA FY 2024 President's Budget, FY 2023 Enacted, and FY 2024 amounts are estimates and subject to change. The funds displayed are non-dedicated budget authority. Final amounts will change depending on regulatory priorities and activities within a given year.

TALKING POINTS:

- The budget includes a mandatory proposal to invest \$9.8 billion over 10 years to create a national financing and delivery program so anyone who needs Pre-exposure Prophylaxis (PrEP) has access via community providers.
- Fewer than 1 in 4 people who could benefit from PrEP are receiving the medication. Preliminary CDC data show that only 9 percent of the nearly 469,000 Black individuals who could benefit from PrEP received a prescription in 2020 and only 16 percent of the nearly 313,000 Hispanic and Latino individuals who could benefit from PrEP received a prescription.

QUESTIONS:

Q: The Budget includes a new PrEP for All proposal. What will happen to the current PrEP donation program?

A: The PrEP for All proposal builds on the current donation program to expand its benefits and purposes to meet anyone in need of care.

Q: What is the future cost of this program?

A: The program invests \$9.8 billion over the next ten years to expand access to PrEP for individuals at high risk of HIV infections across the United States.

Q: Will this program end the HIV/AIDS epidemic?

A: The program aims to end the HIV/AIDS epidemic by 2030, with a commitment to 75% infection reduction by 2025.

Program Integrity

(Dollars in Millions)

Activity	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Discretionary HCFAC			
CMS	666	667	+1
ACL ¹	0	35	+35
OIG	105	112	+7
DOJ	122	122	+0
Subtotal, Discretionary HCFAC	893	937	+44
Mandatory HCFAC	1,523	1,812	+289
Total, HCFAC Program Level	2,416	2,749	+333
Medicaid Integrity Program	95	100	+5

¹ACL's FY 2023 Enacted amount (\$35 million) for the Senior Medicare Patrol program is included in CMS's FY 2023 Enacted amount.

TOPLINE MESSAGES:

- The budget includes \$5.2 billion¹ in new investment over ten years in combined mandatory and discretionary Health Care Fraud and Abuse (HCFAC) spending.
- This robust program integrity investment will yield a return-on-investment of \$19.7 billion over ten years.
- Increased investment is needed to keep pace with the size, scope and complexity of healthcare fraud.
- Without additional resources, CMS, the HHS Office of Inspector General, and DOJ may have to forgo investigating serious instances of fraud, waste, and abuse.

QUESTIONS:

Q: Why are you seeking such a large increase in HCFAC funding? Is this an indication that the Administration has allowed healthcare fraud to run rampant?

- No. The increase in HCFAC funding reflects the Administration's commitment to fighting fraud and the belief that this investment will pay off in significant returns to Medicare Trust Funds and the Treasury.

¹ The printed draft of the Budget in Brief has an error showing this number as \$5.5 billion rather than the correct figure of \$5.2 billion; the on-line version of the BIB will correct that error.

Secretary Xavier Becerra's Version: Fiscal Year 2024 Budget Topic Summaries

- Growth in Medicare and Medicaid benefit spending has been more than double growth in HCFAC oversight spending in the last four years alone.
- Additionally, this funding is necessary to keep pace with the growing scope and complexity of fraud schemes.
- This investment will more than pay for itself. Medicare program integrity activities currently yield an \$8 to \$1 return-on-investment. Law enforcement program integrity activities currently generate a \$4 to \$1 return-on-investment.

Provider Relief Fund

TALKING POINTS:

- The Provider Relief Fund (PRF) was developed and launched mere weeks after the CARES Act passed, at the height of the initial challenges related to the pandemic and at a time of great uncertainty surrounding the impact that COVID-19 would have on the health care system.
- HHS has obligated approximately \$179.5 billion in PRF and American Rescue Plan Act Rural funding. This includes:
 - \$15.4 billion to over 90,000 providers in Phase 4
 - \$8.3 billion in ARP Rural payments to 47,000 providers with patients who live in rural areas
 - Nearly \$20 billion to about 65,500 providers through Phase 3
 - About \$13 billion to safety net hospitals
 - Almost \$21 billion to providers in “COVID-19 Hotspots” at different times during the pandemic
 - Nearly \$5 billion to skilled nursing facilities
- The Biden-Harris Administration implemented Phase 4 of the PRF allocations after the prior Administration had allocated most of the funds. In this Administration, we have focused on distributing PRF payments in a way that recognizes providers’ public payor mix and as efficiently as possible while ensuring transparency and program integrity to safeguard taxpayer dollars.
- To date, of the 106,000 applications received, HHS has **processed more than 99% of Phase 4 applications** and **100% of applications for rural** providers in the American Rescue Plan funding.

QUESTIONS:

Q: How much money is left in the Provider Relief Fund?

- All funding is fully allocated. Balances are supporting ongoing activities.
- HHS has allocated resources to reimburse health care providers for the cost of COVID-related health care through the Provider Relief Fund program. HRSA conducts a thorough, multi-step process to evaluate and verify provider claims and requests for reconsiderations. While most funds have been obligated, in some instances, HRSA’s process is not yet complete. Congress made these funds available until expended. HRSA obligates funds as payments are made.

Q: Why did HHS use PRF funds to promote vaccine confidence and vaccine outreach campaigns in December 2022?

The campaigns launched in December 2022 supported the uninsured and most vulnerable population in accessing COVID vaccines. HHS utilized available funds to support access to critical COVID services during the winter months.

Q: Why is HHS sending debt collection letters to providers for Provider Relief Fund payments?

- PRF recipients are required to comply with reporting requirements established under the CARES Act.
- Providers who do not meet their reporting requirements or who are otherwise found out of compliance with the Terms and Conditions are subject to repayment of the funds.
- HHS has begun issuing Final Repayment Notices to providers who are non-compliant with the PRF Terms and Conditions.
- Providers who disagree with the repayment request have an opportunity to request a Decision Review of HHS's decision to seek recovery of PRF funds. Information on how providers may request a Decision Review will be included in the Final Repayment Notice.

Q: Why did PRF payments appear to benefit providers that were in stronger financial positions at the start of the pandemic?

- Due to the unprecedented nature and uncertainty at the beginning of the pandemic, Congress directed that HHS distribute PRF funds using "the most efficient payment systems practicable to provide emergency payment."
- As a result, HHS used provider data that was readily available, including data already used by HHS agencies, or could be quickly and consistently collected to ensure that payments would be issued swiftly so the health care system could be kept afloat at a time when many health care providers were experiencing an unprecedented and abrupt loss in revenue.
- Ensuring equity and transparency in PRF payments has been a top priority for me.
- Under my leadership, we developed and implemented Phase 4 of the Provider Relief Fund. Phase 4 prioritized equity for providers serving high need communities, including by incorporating bonus payments based on the number of services provided to patients with Medicaid, Children's Health Insurance Program (CHIP), or Medicare coverage, who tend to have greater and more complex medical needs or have lower incomes.

Quality Adjusted Life Years (QALYs)

TALKING POINTS:

- Across HHS, we are working every day to address the health disparities of disabled people and ensure equal access to health care for everyone.
- There is already a prohibition on the use of quality adjusted life years in Medicare, and HHS is in full compliance.
- We are happy to work with Congress and provide technical assistance on legislation related to the use of quality adjusted life years.

If pressed on drug price negotiation

- The Inflation Reduction Act prohibits the Secretary from using quality adjusted life years for drug price negotiation.
- We will follow the statute.

Refugees and Unaccompanied Children – Budget Overview

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Transitional and Medical Services	564	1,000	+436
Refugee Support Services	307	686	+379
Unaccompanied Children	5,506	5,506	--
FY 23 Supplemental Funds	2,400	--	-2,400
FY 23 CR Anomaly Funds	1,775	--	-1,755
Contingency Funds ¹	<u>326</u>	<u>2,776</u>	<u>+2,450</u>
Subtotal, UC & Refugees	10,878	9,969	-910
Trafficking Victims and Torture Survivors	50	66	+17
Total Program Level²	10,928	10,035	-893

¹ Funding amounts are based on probabilistic scores

² FY 2023 includes \$2.4 billion in Division M (Ukrainian Supplemental) funds which are not included in budget authority.

TALKING POINTS:

- The budget provides \$10.0 billion for new arrivals and unaccompanied children. An expanded contingency fund would provide additional resources if needed for either population.
- Refugees: Continues to **rebuild the nation's resettlement capacity** by requesting an increase of +\$815 million to support 241,000 eligible new arrivals in FY 2024, including 125,000 refugees.
 - Including the contingency fund, the Budget would support 426,000 new arrivals.
- Unaccompanied Children: **Protects** unaccompanied children, moving them from the DHS border facilities to child center care settings, keeping them safe from COVID, and uniting them safely and quickly with vetted relatives or other sponsors.

QUESTIONS:

Q: Does your budget include sufficient funds to shelter all new arrivals and unaccompanied migrant children?

A: Budgeting for this program is challenging because we do not know how many people will need services in FY 2024. Because these estimates may change, it also includes a contingency fund to ensure we can respond to the unpredictable and sometimes rapidly changing nature of these populations.

- Protecting unaccompanied migrant children can be costly given their complex needs and various legal and ethical requirements. We are focused on being good stewards of tax dollars without cutting corners when it comes to the well-being of children in our care. We also owe new refugees, asylees, and other arrivals a chance to become self-supporting in their new home country.
- The budget includes sufficient discretionary funds to provide initial support for 241,000 new refugee, asylee, and other arrivals and for 16,000 standard shelter beds.
- If additional resources are needed for either population, the Budget proposes an expanded version of the contingency fund Congress enacted in FY 2023.
 - Unaccompanied Children: Funds would be provided if monthly arrivals exceed 10,000 in FY 2024.
 - New Arrivals: Funds would be provided if the number of Asylees and Cuban and Haitian entrants exceeds 150,000 in FY 2023 or 75,000 in FY 2024. Unlike refugees, these populations are not subject to a ceiling.

Q: Will HHS need a supplemental or be deficient before the end of FY 2023?

A: I appreciate the question. I would like to express my gratitude to Congress for providing \$10.9 billion for refugees and unaccompanied children in the FY 2023 Omnibus, \$2 billion more than the FY 2022 amount and for approving a contingency fund for Unaccompanied Children. That said, arrival numbers through February have been as high as they were in FY 2022 and the future impact of title 42 termination on referral numbers is uncertain. We will continue to assess our funding needs and operational options, and to communicate with the Congress.

Q: What is HHS doing to combat child labor exploitation among unaccompanied children?

A: HHS continues to work hard to protect the safety and wellbeing of unaccompanied children by providing them child-centered care while they are in our custody and follow up services after they are released. Last month, the Departments of Labor and Health and Human Services announced a series of actions to increase their efforts to thoroughly vet sponsors of migrant children, investigate child labor violations, and hold the companies accountable. HHS activities include:

- **Mandated Follow Up Calls for Unaccompanied Children Who Report Safety Concerns:** HHS will require a follow-up call to any child who calls the Office of Refugee Resettlement National Call Center with a safety concern.
 - The Center currently refers every safety related call to the appropriate law enforcement or child protective services agency.
 - This additional call will serve as a critical follow up with the child.
- **Expand Post Release Services for Unaccompanied Children:** HHS continues to increase the percentage of children receiving services and to improve their quality.

- HHS provided post release services to more than 40 percent of discharged children in FY 2022, nearly double the percentage receiving services when the Biden Administration took office. HHS is on track to provide services to all children who would benefit from post release services within the next two years.
- Additional post release services include assistance in registering children for school, ensuring they understand the immigration legal process and can attend their court hearings, and help finding medical, mental health, and family counseling services for which they may be eligible.
 - ACF will publish a new grant announcement this spring, expanding *eligibility* for post release services to all discharged children and establishing a new service level for specific challenges or special circumstances (e.g., medically or psychologically vulnerable children, family conflict or crisis, education-related issues).
- **Audit Sponsor Vetting Process:** HHS is auditing the vetting process for potential sponsors who have previously sponsored an unaccompanied child to ensure all necessary safeguards are in place without unnecessarily keeping children in shelter care.
 - This audit builds on steps that HHS has already taken to increase vetting of those types of sponsors and includes updates to data systems to identify such cases more easily.

Refugees - Afghan/Ukrainian

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Transitional and Medical Services (TAMS)	564	1,000	+436
Refugee Support Services	307	686	+379
CR Emergency Supplemental	1,775	0	-1,775
Division M Supplemental	2,400	0	-2,400
Contingency Fund	326	2,776	+2,450
Trafficking Victims and	31	39	+9
Torture Survivors	19	27	+8
Total Program Level, Refugees¹	5,442	4,529	-893

1 Excludes funds for Unaccompanied Children

TALKING POINTS:

- In the 18 months since the launch of Operation Allies' Welcome (OAW), the U.S. has welcomed approximately 94,000 individuals from Afghanistan, and over 120,000 Ukrainians are part of Uniting for Ukraine (U4U) all eligible for ORR benefits and services.
- ORR continues to fund services through the \$2.9 million ASA supplementals and a \$900 million supplemental supporting Ukrainian arrivals. These supplementals have provided cash and medical assistance, emergency housing, support for schools and enhanced mental health services.
- We are working to support longer-term housing and support legal assistance to Afghans as they pursue permanent asylee status.

Refugees - Cuban/Haitian/Venezuelan Parole Program

TALKING POINTS:

- ORR strives to ensure equitable access to benefits and services for all ORR-eligible individuals. Cuban and Haitians coming through the new parole program are eligible for ORR services supporting their path to self-sufficiency.
 - Over 20,000 Cuban and Haitians have arrived through the new parole program.
 - The FY24 budget assumes 241,000 new arrivals eligible for refugee benefits for the year, including 116,000 non-refugee arrivals such as Cuban and Haitian entrants.
 - These individuals are eligible for ORR refugee benefits and services and are also eligible to apply for work authorization and a Social Security number.

If pushed on FY203 supplemental funding:

- ORR received \$2.4 billion in FY 2023 supplemental funding to support the impact of increased arrivals as well as unaccompanied children. ORR is working to allocate these funds to impacted areas providing cash and medical assistance and other Refugee Support Services to include employment and language supports.
 - Budgeting for these programs is challenging because the number of people they serve fluctuates. The budget request includes a contingency fund which could provide support to 426,000 new arrivals.

Reproductive Health

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Title X Family Planning (HRSA Discretionary)	286	512	+226
Teen Pregnancy Prevention (GDM Discretionary)	101	111	+10
Sexual Risk Avoidance (GDM Discretionary)	35	--	-35
Embryo Adoption Awareness Campaign (GDM Discretionary)	1	1	--
Teen Pregnancy Prevention Program Evaluation (PHS Evaluation Funds)	7	8	+1
Total Program Level	430	632	+202

TALKING POINTS:

- Since Title X was created, **more than 195 million predominantly low-income clients** have received quality healthcare through Title X as their usual source of medical care, including the services, information, and referrals, that higher-income clients and clients with private insurance get.
- 3,284 community-based sites have provided clinical and educational services to **over 1.7 million persons** in 2021 (most recent year available) through 2.8 million family planning encounters.
- Title X has long been the gold standard of family planning care, and this administration has re-doubled its **emphasis on quality by realigning the program's requirements with national clinical recommendations** on delivering quality family planning services.
- Title X offered cervical and breast cancer screening services to over 320,000 female users and funds sexually transmitted disease and HIV testing for preventing disease transmission and adverse health consequences.
- In 2021, 86% of clients had family incomes at or below 250% of the FPL, and 65% of all clients were entitled to free services with incomes at or below 100% FPL.

QUESTIONS:

Q: Why is the Sexual Risk Avoidance program being eliminated in FY24?

A: Proponents of adolescent health, including prevention of teenage pregnancy, strongly oppose this program because of the lack of evidence that it works and have expressed concern that it could rather have adverse impact on overall teenage health and behavior. The FY24 budget shifts this funding into the evidence-based Teen Pregnancy Prevention program and Title X Family Planning program, continuing support for vulnerable populations with proven and effective programming.

Q: Will these funds be used to provide abortion services?

A: The Title X program does not provide abortion services. Section 1008 of the Public Health Service Act specifically states that “None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.” Consistent with the program’s statute and regulations, any public or private nonprofit organizations, including faith-based organizations, state, county, local, and tribal governments, school districts, and public and state higher education institutions are eligible to apply for Title X grant funds. Title X’s regulations also clearly define the criteria the Department uses to decide which family planning services projects to fund and in what amount.

Q: The 2021 Title X final rule argued that it was necessary to restore and expand access to Title X family planning services. Has the administration succeeded in getting new providers and what is the impact on funding for loyal family planning grantees that did not leave the program since there was no increase in funding?

A: The demand for Title X funding for highly qualified providers to deliver care in communities far exceeds the resources available.

- A federal study from 2016 estimated that Title X would need \$737 million to serve just all of the women in need of Title X care.
- The reality is that it has been eight years since there was an increase for Title X through the annual appropriations process.
- As a result, the Department has had to make tough choices with a focus on ensuring that as many clients in as many communities can get the quality family planning care they want and need.

Q: What is HHS doing to protect individual’s rights to reproductive care as we see attacks across the country?

A: HHS has taken several meaningful actions under the Biden-Harris Administration to protect and bolster reproductive health, rights, and justice.

- In October 2021, we issued a final rule for the nation’s family planning program to strengthen access to equitable, affordable, client-centered, and high-quality family planning services nationwide.
- In January 2022, we announced \$6.6 million for the Title X planning program to address demand for family planning services where restrictive laws and policies have impacted reproductive health access.

Q: Maternal Mortality surged by nearly 20% during the first year of COVID-19 (2020), and the gap between black and white maternal mortality grew. What is HHS doing to reduce these disparities and address this maternal crisis in the US?

A: This is a key priority for me personally and the Biden-Harris Administration.

- Thanks to the American Rescue Plan, we have worked with states to expand Medicaid coverage of postpartum health care for 12 months. Illinois, Georgia, Missouri, New Jersey and Virginia have led this important initiative.
- We increased funding for Enhancing Reviews and Surveillance to Eliminate Maternal Mortality Program to reach six additional states, for a total of 30 awards supporting 31 states. This funding directly supports agencies and organizations that coordinate and manage Maternal Mortality Review Committees (MMRCs) to identify, review, and characterize pregnancy-related deaths; and identify prevention opportunities.

The 2021 Title X final rule revoked requirements of the 2019 regulations, including removing restrictions on nondirective options counseling and referrals for abortion services and eliminating requirements for strict physical and financial separation between abortion-related activities and Title X project activities. Will this change lead to use of federal funds to pay for or promote abortion services?

- The 2019 Trump Administration regulations substantially diminished the Title X family planning network by forcing requirements inconsistent with nationally recognized clinical recommendations. The impact of both the Trump Administration's regulations and the pandemic led to a drop in the number of clients served from 3.9 million to 1.5 million people. The new regulations restore many aspects of the program that were removed through the Trump administration regulations.
- The final Biden Administration Title X regulations allows all highly qualified family planning providers, including clinics like Planned Parenthood that provide abortion services outside of Title X with non-federal funds, to once again apply for federal support to provide family planning services to low-income and uninsured individuals.
- Advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, is a priority for the Administration, including the Title X program and the Department. This 2021 regulation will allow for the Title X service network to expand in size and capacity to provide quality family planning services to more clients.
- As outlined by the Title X statute and reinforced in its regulations, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." Consistent with the program's statute and regulations, any public or private nonprofit organizations, including faith-based organizations, state, county, local, and tribal governments, school districts, and public and state higher education institutions are eligible to apply for Title X grant funds. Title X's regulations also clearly define the criteria the Department uses to decide which family planning services projects to fund and in what amount.

Return to Work

TALKING POINTS:

- The COVID-19 pandemic reshaped the workplace for many Americans, including federal employees at HHS.
- While COVID-19 is no longer a determining factor for how we do our work, the pandemic has forever changed both the public and private sectors' approaches to the way work is done. Hybrid work environments have allowed federal agencies, including HHS, to stay competitive with other sectors, ensuring we are recruiting and retaining the best talent to help meet the needs of the American people.
- Federal agencies, including HHS, are strategically using personnel policies like telework, remote work, and flexible work schedules to advance their missions and better compete in the national labor market to attract and retain a well-qualified and engaged federal workforce.

QUESTIONS:

Q: How many days were you personally in the office last week?

I can assure you that this is a 24/7 job and I treat it as such, whether I am in the office or the on the road helping advocate and elevate the work of HHS and our incredible divisions.

Q: In last year's SOTU, President Biden said "the vast majority of federal workers will once again work in person." Yes or no, are the vast majority of your employees working fulltime in person today?

- Our employees are working fulltime.
- HHS is unique in that the Department has thousands of mission critical employees who never left their worksites, even at the height of the COVID-19 pandemic. Together with those employees working remotely, HHS continues to meet its mission for the American public.
- Some individuals are on-site full-time, the majority of the workforce reports to their workplace every pay period, and some workers are fully remote. Regardless of an employee's physical location, they continue to work hard every day to carry out the mission of HHS.
- I would also note that we have scientists in labs and service providers in the field working hard every day who may or may not be regularly logging into systems, depending on their work's needs.
- *If pressed on numbers:* I do not have those numbers on hand and would note this is not a static situation.

Q: Do you believe HHS's mission is hindered by having so many employees working remotely?

- In just the last two years, HHS and its operating divisions have accomplished incredible work for the American people, including:
 - The roll-out and distribution of 294 million vaccines doses to 75,000 sites across the country as well as 670 million at-home COVID-19 test kits-.
 - The largest and most successful open enrollment to date in 2022 with 14.5 million people signed up for or enrolled in Marketplace coverage.
 - Increased provider access to buprenorphine, the medication assisted treatment for opioid use disorder, by 21% from 2021 to 2022.
 - Transition to the 988-suicide prevention lifeline – an easy-to-remember number for 24/7 crisis care.
- All these accomplishments, which are just a snapshot of HHS' work, occurred while the agency offered a telework or hybrid posture for some employees. These milestones reflect how the Department continues to deliver for the American people and promote the health and well-being of the nation.

Rural Health

	FY 2023	FY 2024	
	Enacted	President's Budget	+/- FY 2023 Enacted
Rural Health Policy Development	11,076	11,076	-
Rural Health Outreach Grants	92,975	95,375	+2,400
Rural Hospital Flexibility Grants	64,277	64,277	-
State Offices of Rural Health	12,500	12,500	-
Radiation Exposure Screening and Education Program	1,889	2,734	+845
Black Lung	12,190	12,190	-
Rural Communities Opioid Response	145,000	165,000	+20,000
Rural Residency Planning and Development	12,500	12,700	+200
Rural Health Clinic Behavioral Health Initiative	-	10,000	+10,000
Financial and Community Sustainability for At-Risk Rural Hospitals	-	10,000	+10,000
The Rural Hospital Stabilization Pilot Program	-	20,000	+20,000
Subtotal, Federal Office of Rural Health Policy	352,407	415,852	+63,445

TALKING POINTS:

- Health care should be accessible, no matter where you live.
- The Biden-Harris Administration is dedicated to improving access to health care in rural communities and addressing the issues which contribute to health inequities impacting these communities.
- Thanks to Congress's leadership in the Consolidated Appropriations Act of 2021, CMS has implemented a new Medicare provider type, the Rural Emergency Hospital. Applications are available now for hospitals in rural areas that would like to change to this new provider type.
- Over the last two years, through the Rural Communities Opioid Response (RCORP) program, we have served over two million rural individuals.

- The President's Budget seeks to support and expand these programs to ensure every person has the same level of care no matter their zip code.

QUESTIONS:

Q: We have seen large increases in costs for hospitals, including labor costs. Are you aware of this issue, and do you believe it may be time to update the method for reimbursing hospital labor costs to better reflect new staffing practices?

- HHS is committed to promoting Medicare payment accuracy and hospital stability.
- In computing the Hospital Wage Index, CMS follows a process established by law. In applying the law, CMS strives to ensure access for all beneficiaries while maintaining incentives for the agency's hospital partners to operate efficiently.
- The goal of the hospital wage index is to adjust hospital payment rates to account for local differences in the wages.

Q: Which telehealth services will no longer be covered under Medicare after the public health emergency is over?

- Thanks to the Consolidated Appropriations Act of 2023, many telehealth flexibilities available during the public health emergency have been extended through December 31, 2024.
- *If needed:* I would be happy to have my colleagues in CMS follow up with you on questions about specific waivers.
- For over 36 years, HHS has played a leading role in improving the health and well-being of rural Americans.
- HHS funds a range of programs that directly support rural communities to increase access to care in rural communities, build the infrastructure necessary to implement the services, and train and expand the workforce in rural communities.
- Additionally, HHS supports the only federal research program specifically focused on rural health issues.
- Our Budget requests a \$63 million increase for rural programs, which is critical amid ongoing challenges of health care access and disparities.

Q: How does HHS plan to utilize the requested budget increase for rural health programs?

- HHS is requesting \$20 million to continue to support substance use disorder prevention and treatment in rural communities including the creation of new medication assisted treatment access points and equipping first responders with naloxone.
 - o The Rural Communities Opioids Response program funds prevention, treatment, and recovery services in rural communities, serving over two million rural individuals between 2021 and 2022.
 - o We plan to reach even more rural individuals with this increased funding.

- In addition, we are requesting \$40 million for three new programs to meet the unique health needs of rural communities as they face hospital closures and service reductions exacerbating disparities in access to care.
 - o \$10 million for the Rural Health Clinic Behavioral Health Initiative which aims to expand access to behavioral health care services at Rural Health Clinics;
 - o \$10 million for Financial and Community Sustainability for At-Risk Rural Hospitals which targets technical assistance to rural hospitals at-risk for closure; and
 - o \$20 million for the Rural Hospital Stabilization Pilot Program to enable at-risk hospitals to expand their services, such as obstetric services, chemotherapy, and more, to create new care in the community while expanding revenue streams to stabilize operations and meet local needs.

Shortages/Supply Chain Issues

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
FDA ¹	10	22	+12

¹ Funding is specific to continue building capabilities for the supply chain and shortages program for medical devices.

TALKING POINTS:

- We continue to take steps to closely monitor the supply chain and address shortages to help protect Americans' access to critical medical products. As you know FDA is limited in its authorities to prevent and resolve shortages.
- Right now the FDA can:
 - Assist with production by expediting reviews of new marketing submissions, production lines, or material sources to increase production;
 - Extend Product expiration dates by reviewing requests for extensions of product expiration dating; and
 - And exercising temporary regulatory flexibility and discretion.
- The budget invests **\$26 million** in ongoing efforts to modernize the agency's safety surveillance and oversight program, mitigate supply chain interruptions, and enhance active surveillance system for medical devices.
- We are also requesting important new authorities to enhance FDA's ability to forecast, prevent and resolve the supply chain challenges. Such as a requirement for manufacturers to alert FDA when there is an increase in demand of a product, as we saw this past year.

QUESTIONS:

Q: How does the Agency prevent or respond to drug shortages?

- As a result of presidential, congressional, and FDA actions, drug manufacturers are notifying FDA earlier than in the past about certain manufacturing interruptions and discontinuances.
- These early notifications give FDA additional time to work with manufacturers and other stakeholders to identify ways to maintain treatment options and prevent or mitigate a shortage.
- FDA helps prevent and resolve drug shortages in various ways such as: expediting reviews of new production lines or material sources to increase production; reviewing requests for extensions of product expiration dating; and exercising temporary regulatory flexibility and discretion.

- FDA has been able to help prevent shortages, but we are seeing continued challenges and hearing from manufacturers frequently about potential disruptions in their supply and from patients who cannot find the medical products they need.
 - Manufacturers are not expressly required to notify FDA when a shortage is due to increased demand.
 - Having early indication of increases in demand may allow the Agency to better utilize our authorities associated with drug shortages and work with manufacturers to help avoid unnecessary drug shortages driven by demand.
 - Many underlying causes of shortages are likely related to economic/market forces that go beyond a regulatory agency's jurisdiction. FDA cannot order manufacturers to continue making a product or to make more of the product. Nor can FDA tell them how to distribute their products.

Q: How does the Agency prevent or respond to device shortages?

- FDA's authorities for medical device shortages remain limited.
- As a result of the CARES Act of 2020, manufacturers of critical devices have, during the COVID-19 public health emergency, been notifying FDA about certain manufacturing interruptions and discontinuances.
 - These notifications have given FDA more timely information to work proactively with manufacturers and other stakeholders to identify alternative sources of raw materials and device components and work through other supply chain issues.
- FDA helps prevent and mitigate device shortages in various ways such as: expediting reviews of new marketing submissions, expediting inspections, granting emergency use authorizations, and exercising temporary regulatory flexibility
- During the public health emergency, FDA used the information we collected under these new authorities to help prevent or mitigate approximately 350 of the 455 device shortages or potential shortages that emerged.
 - Unfortunately, FDA's authority to require notifications from manufacturers of critical medical devices is temporally limited to "during or in advance of" a public health emergency, and will lapse when the public health emergency declaration expires.
 - COVID-19 also showed us that manufacturers are not always prepared for situations where their ability to manufacture product may be disrupted or may be insufficient to meet increases in demand. Providing FDA clear authority to review risk management plans (RMPs) would help ensure resiliency and mitigate future supply chain disruptions.

State Opioid Response (SOR) Grants

TALKING POINTS:

- Since the State Opioid Response (SOR) program began, approximately 1,148,900 patients have received treatment services, including almost 553,350 who have received an FDA-approved medication for opioid use disorder.
- The budget provides \$5.7 billion for SAMHSA's substance use prevention and treatment activities, an increase of \$1.3 billion over FY 2023 enacted, funding states and territories to increase access to treatment for substance use disorder, advance public-health interventions like naloxone, and expand recovery support services.
- The budget request for the SOR program at the FY 2024 budget level (\$2 billion) would enhance states' ability to address opioids and stimulants and respond to the overdose epidemic that have been exacerbated due to the COVID-19 pandemic.
- We understand the importance of avoiding funding cliffs across all states as we develop the next iteration of the formula. Ultimately, we want to help states address their needs.

QUESTIONS:

Q: Overdoses continue to skyrocket. Can you please explain what the State Opioid Response funds are used for and any accomplishments from last year?

- The SOR program provides funding to states and territories to implement strategies that prevent, intervene in, and promote recovery from issues related to opioid use and misuse and stimulant use.
- In FY 2022, SAMHSA awarded base State Opioid Response grants to 58 states and territories via a formula. The program includes a 15 percent set-aside for states with the highest mortality rate related to drug overdose deaths.
- Since the program began, states report that approximately 1,148,915 patients have received treatment services, including 553,347 who have received an FDA-approved medication for opioid use disorder.
- Through the program, 97,768 patients received treatment services for stimulant use disorder and 1,171,670 patients received recovery support services.
- It is also important to note that SAMHSA also provides Tribal Opioid Response grants through this program, which addresses the public health crisis of escalating opioid misuse and overdose in Tribal communities. In FY 2022, SAMHSA awarded \$55 million in TOR grants.
 - Since 2018, Tribes and Tribal organizations have provided TOR-funded treatment and recovery support services to 7,700 clients. Tribes have also purchased and distributed 16,955 naloxone kits and 7,045 fentanyl testing strips and trained 3,357 community members on the use of lifesaving naloxone.

Q: As you work to administer State Opioid Response grants this year, will you commit to working with me to ensure that small changes in a state's ranking in opioid overdose deaths do not result in large-scale reductions in funding?

- The State Opioid Response Grant program is a critical program helping states address the overdose epidemic. For the FY 2022 and FY 2023 SOR awards, SAMHSA held states harmless for pandemic-related factors and a data definitional change for substance use disorders that occurred in 2020.
- We understand the importance of avoiding funding cliffs across all states as we develop the next iteration of the formula. Ultimately, we want to help states address their needs.

Q. Fatal and non-fatal overdoses on Native American Reservations are typically higher, can you share any data on what the Tribal Opioid Response (TOR) grants were used for last year?

- In FY 2022, SAMSHA funded 102 new Tribal Opioid Response grants. Since 2018, Tribes and Tribal organizations have provided Tribal Opioid Response-funded treatment and recovery support services to 7,700 clients.
- Tribes have also purchased and distributed 16,955 naloxone kits and 7,045 fentanyl testing strips and trained 3,357 community members on the use of lifesaving naloxone.
- Tribes and Tribal organizations funded through TOR also educated over 25,000 individuals on the consequences of opioid misuse and overdose through prevention activities.

Surprise Billing

TALKING POINTS:

- I would like to start by again thanking Congress for its leadership in enacting this law to protect patients from surprise billing in health care. Patients and their families deserve the security of knowing they are kept out of the middle of disagreements between insurers and providers. HHS—together with our colleagues at the Department of Labor, Department of the Treasury, and Office of Personnel Management—has been working to implement the No Surprises Act and ensure that consumers receive the benefits of the protections included in the law by Congress.
- We are committed to continuing to protect patients from crippling medical bills and increase transparency in our health care system. That is why this Administration is requesting \$500 million to replenish and extend the No Surprises Act Implementation Fund.

If pressed on the current status:

- Because of a recent court order, IDR entities are holding issuance of payment determinations that involve items or services delivered **on or after October 25, 2022** until the Departments issues further guidance.
- The Departments are working diligently to complete necessary guidance and system updates in order to allow certified IDR entities to resume processing payment determinations for these disputes.
- Disputes involving items or services furnished **before October 25, 2022** are proceeding.

QUESTIONS:

Q: There is concern about the provider burden and impact of an increased administrative fee. Can you give additional detail on the methodology and rationale for the administrative fee increase?

- As you know, we released an initial public report on the Federal IDR process and an updated administrative fee guidance document for 2023. There are two big trends.
 1. First, there is a very high volume of disputes being submitted for resolution, significantly more than we or the IDR entities anticipated or were staffed for. For example, through December 5th of last year, there were over 160,000 disputes submitted through the portal.
 2. Second, IDR entities have had to perform a substantial amount of outreach and analysis to determine whether a dispute is eligible for the Federal IDR process.
- The high volume and complexity of this work was taking away from IDR entities' ability to review bona fide disputes and the structure of the No Surprises Act regulations prevents IDR entities from being compensated for cases that are not eligible.
- We've taken steps to help address some of the ongoing challenges created by the large initial volume of disputes to allow IDR to focus on making payment determinations, including making sure the administrative fee covers "pre-eligibility" actions and setting

that fee at a level that covers the estimated annual cost of operating the Federal IDR process and working on system changes and considering policy options that will allow us to reduce the IDR administrative fee in the future and make the process smoother for everyone.

Q: Why is the Administration requesting additional funds for No Surprises Act implementation?

- To implement the No Surprises Act, the Departments scaled up expertise and resources for rulemaking, technical builds, enforcement, and staffing.
- A one-time lump-sum appropriation of \$500 million was provided to the Departments for implementation of the No Surprises Act and Title II Transparency provisions.
- While the original appropriation expires at the end of 2024, most of the statutory requirements added by the No Surprises Act and Title II Transparency provisions are permanent and the Departments will have ongoing responsibilities such as enforcement of plan, issuer, and provider compliance; complaints collection and investigation; as well as auditing comparative analyses of non-quantitative treatment limits for mental health and substance-use disorder plan benefits.
- While some activities, particularly those around the Federal IDR process, are supported through a separate administrative fee, many other activities implementing the No Surprises Act are not.
- Factoring in cost projections for those activities that the Departments are currently undertaking, the Departments project that the No Surprises Act Implementation Fund will be exhausted before the end of calendar year 2024. The continued implementation of these provisions will have to compete against other agency priorities and initiatives, especially as funding for certain appropriations, such as for CMS Program Management, haven't kept pace with the increasing responsibilities that have been delegated to the agencies.

Q: A recent article suggests that there may be a loophole in the No Surprises Act allowing providers to remain out-of-network while contracting with plans as a 'participating' provider, thereby exposing patients to out-of-network coinsurances for services, including when they have not received notice or provided consent to those services or charges. What is HHS doing to evaluate this potential loophole and ensure that it is not impacting patients?

Patients and their families deserve the security of knowing that their coverage will be there for them when they need it. We are investigating the issues raised in the article. We take seriously the effective implementation of the law as intended to protect consumers from surprise medical bills, and we value your feedback as we do so.

Q: We have heard from stakeholders that payments to the winning party in an IDR dispute are not being made in a timely manner in accordance with the requirements of the No Surprises Act. What is HHS doing to enforce the requirement that any payment owed by a health plan or provider as a result of an IDR decision is being made promptly?

- Our regulations require that the losing party remit payment within 30 days of a payment determination. If the prevailing party believes that the non-prevailing party isn't complying with the payment requirements with the dispute resolution process, then we encourage them to contact the No Surprises Help Desk to submit a complaint.
- We are investigating the complaints that we have received on this issue.

Q: Does CMS intend to release the findings of their Qualifying Payment Amount (QPA) audits, in addition to submitting a report on these audits to Congress as required by the No Surprises Act?

- We are conducting qualifying payment amount (QPA) audits to ensure that plans are complying with requirements related to its calculation and disclosure.
- The Departments are actively conducting QPA audits as required under the statute and intend to produce the reports to Congress required.

TANF

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Mandatory Program Funding	17.3B	17.3B	
Proposal Impact to TANF	-	5	5
Proposal Impact to TANF Contingency Fund	-	(5)	(5)
Total Program Level	17.3B	17.3B	-

TALKING POINTS:

- The Department shares your commitment to an effective safety net system that ensures funds are spent to accomplish a TANF purpose and welcomes the opportunity to work with you to strengthen TANF.
- TANF is intended to serve as a critical support to families experiencing economic hardships, providing cash assistance, employment and training assistance, and related services to ensure families can meet basic needs, get access to opportunities in the job market, and remain together; and we must strengthen the program so that it can meet its purposes and continue to support families and communities.
- We will continue to support all grantees in strengthening policies and practices that effectively invest in basic assistance and family supports with program integrity and accountability.
 - The Department is requesting new statutory authority in the TANF program to increase transparency with respect to TANF spending and implement program integrity measurement across the program.
 - Increased monitoring of TANF expenditures and their alignment with allowable uses of block grant funds are necessary to ensure that TANF functions as it was intended – as a critical support to families experiencing economic hardships, providing cash assistance, employment and training assistance, and related services so that families can meet basic needs, get access to opportunities in the job market, and remain together. ACF wants to collect data to improve monitoring of allowable uses of funds.
 - Congressional action is needed to equip the Department to fully implement additional program integrity measures. We welcome the Committee's partnership in supporting these requests.

QUESTIONS:

Q: Mississippi has been in the news for the large-scale conspiracy and embezzlement of millions of dollars in TANF funding involving the Mississippi Department of Human Services. How are largescale abuses like this happening under HHS' watch?

- As has been reported in the news media, multiple Federal and State agencies are continuing to review this case.
- While we are unable to share specifics on the ongoing assessment of misuse of funds in Mississippi, we do want to reaffirm our commitment to ensuring the highest degree of accountability and integrity within the TANF program nationally.

Q: What is the Department doing to recover taxpayer dollars?

- The Department will work to recover any misused TANF funds from the state. Federal law requires that a state replace with its own state funds any federal TANF funds subject to penalty because the funds were misused.
- When the Department has a complete assessment of the extent of the fraud and misuse, we intend to pursue all appropriate measures, including a TANF penalty, if warranted. The Department does not recover funds directly from individuals or a state's subgrantees.

Q: The Mississippi case demonstrates that state misuse of TANF funds is rampant. Can you speak to how the program has strayed from Congressional intent? Has HHS conducted a systematic review to identify areas of fiscal, administrative, or programmatic weaknesses in the TANF program?

- More than 26 years since TANF was established, state programs have shifted away from a focus on direct cash and employment assistance—services we know make the biggest impact on reducing family and child poverty and are reaching the fewest number of families since passage of welfare reform.
- At the same time, states are using TANF funds on a wide range of benefits and services that have tenuous connection to the statutory purposes of TANF and Congressional intent, including funding for activities without regard to the income or parental status of the recipient.
- HHS has limited oversight of state TANF programs. When possible, HHS uses existing tools to oversee the program, such as Single Audit Reports and other reporting mechanisms. HHS has conducted periodic improper payment risk assessments and works to address weaknesses identified as part of that process (as well as through other oversight mechanisms).
- We intend to pursue all options within our authority to ensure allowable expenses align with TANF purposes.

Q: Has HHS conducted a systematic review to identify areas of fiscal, administrative, or programmatic weaknesses in the TANF program?

- Due to statutory limitations on information that HHS is able to collect from states, the Single Audit report is a key oversight and monitoring tool for the TANF program. Single Audits assess if states have complied with program requirements for areas including

allowable activities, allowable costs, cash management, eligibility, reporting, period of availability of funds, procurement, and sub-recipient monitoring.

- ACF staff thoroughly review the Single Audit reports to determine the need to assess any TANF penalties, as required by statute, as well as to identify areas where states may need additional supports and technical assistance to remediate any weaknesses in internal controls.
- HHS has also completed a TANF improper payment risk assessment, which is used to identify areas of additional risk mitigation.

Q: Does the Department have processes in place to measure and report the amount of improper payments in the TANF program?

- Statutory limitations preclude HHS from collecting information needed to calculate and report a national TANF improper payment error rate.
- This constraint significantly limits ACF's ability to request data needed to calculate a national error rate.
- However, the proposal included in the FY 2024 President's Budget Request, if enacted, would allow ACF to collect data elements pertaining to a range of TANF expenditures, including subrecipient payments for benefits and services, and allow the agency to calculate and report a more robust national TANF error rate estimate.

Title 42

TALKING POINTS:

- Title 42 permits the Director of the CDC to prohibit the introduction of persons when there is serious danger of the introduction of a communicable disease into the United States—and also to aid in continued efforts to mitigate spread of that disease.
- Based on the latest public health information at the time, CDC terminated all Title 42 orders in April 2022.
- However, as you know, the Title 42 Order remains in place due to court order.
- The public health system whether through Title 42 or any other measure is not a replacement for meaningful immigration reform, and it is incumbent upon Congress to come together and find a comprehensive solution.

QUESTIONS:

[Defer questions on DHS readiness to DHS]

Why is the Department not using Title 42 to stop Fentanyl from coming across the border?

- The authority under Title 42 is rooted in protecting public health in regard to communicable disease.
- While the public health emergency for the opioid crisis is ongoing and we have grave concerns about the increase in overdoses, drug interdiction, drug trafficking, and drug use are outside the scope of Title 42.

Tobacco

(Dollars in Millions)

	FY 2023 Enacted	FY 2024	
		Budget	+/- FY 2023 Enacted
Tobacco User Fees	712	812	+100

TALKING POINTS:

- HHS and FDA are laser focused on protecting children from the harms of tobacco use. Since 2019, e-cigarette use among youth has been **reduced by almost 50 percent**.
- FDA has taken significant enforcement actions against e-cigarette companies in the last year, issuing taken action on **99% of the 26 million** e-cigarette product applications. FDA has issued over **1.2 million market denial orders**, and for the first time ever issued civil monetary penalties against e-cigarette companies in violation of the law.
- The Budget provides \$780 million in tobacco user fees to invest in product review and evaluation, research, compliance and enforcement, public education campaigns, and policy development.
- To enhance the regulation of these products and to better protect our children, the budget proposes an additional **\$100 million** in tobacco **user fees**, and provides FDA with the authority to assess user fees from manufacturers and importers of all deemed products.
- This investment will support **Center for Tobacco Product's five-year strategic plan** and comprehensive policy agenda; optimize the application review framework; support additional action to remove illegal products from the market; and enhance public communications and transparency around our work.

QUESTIONS:

Q: How will FDA improve consistent regulation of the tobacco industry?

- We've made important progress and reached science-based regulatory decisions across a broad array of products in the 13 years since Congress tasked the FDA with regulating tobacco products.
- And yet, while the current cigarette smoking rate is the lowest in history, we are faced with significant challenges because of the evolving use of tobacco products, especially in the e-cigarette industry.
- FDA plans to release a five-year strategic plan and comprehensive policy agenda; optimize the application review framework; take additional action to remove illegal

products from the market; and enhance public communications and transparency around our work.

- It's imperative that we are able to meaningfully implement transformational regulations and make decisions based on the public health standard in the law, with the American public – not the interests of the tobacco industry – at the forefront.
- These efforts could be bolstered by the budget proposal to increase user fee collections by \$100 million, which ensure all manufacturers support appropriate regulation of tobacco products.

Topic: Rural Emergency Hospitals (REHs)

- Thanks to Congress's leadership in the Consolidated Appropriations Act of 2021, CMS has implemented a new Medicare provider type, the Rural Emergency Hospital, to address the growing concern over closures of rural hospitals.
- Applications are available now for hospitals in rural areas that would like to change to this new provider type.
- The REH designation provides an opportunity for Critical Access Hospitals and certain rural hospitals that generally do not provide acute care inpatient services to avert potential closure.
- By converting to an REH, eligible rural facilities are able to provide emergency services, observation care, and additional medical and health outpatient services.
- In January 2023, CMS issued guidance regarding the REH enrollment and conversion process for eligible facilities. Some hospitals have already converted to this new provider type in 2023.

UC - Contracts for Border Services/Facilities

TALKING POINTS:

- When it comes to contracts for border services and facilities, ORR operates under the same child welfare principals that guide its core mission. Safety and well-being are at the forefront of every decision we make at HHS.
- In FY 2021, ORR faced a dramatic increase in referrals of Unaccompanied Children. Due to the need to urgently increase ORR's capacity to protect the tens of thousands of children in its care in the face of exceptional circumstances, HHS employed contracting authorities that allow federal agencies to limit competition in certain urgent circumstances.
- This was designed to avoid unacceptable delays in fulfilling ORR's need to expand its bed capacity, including by standing up emergency intake sites (EIS), to protect the safety and well-being of the children in its care.
- Through improvements in case management services across the network, increased staffing, and success of COVID-19 mitigation measures, by spring 2022, ORR was able to open back up standard network capacity, which made reliance on EIS less necessary.

QUESTIONS:

Q: HHS has awarded Family Endeavors, Inc. more than \$1 billion to provide certain facilities and services for the UC program. These contracts were not competitively awarded, and they went to a company that months earlier had hired an individual who served on President Biden's transition team. Do you think it's acceptable to award taxpayer dollars based on political support like this?

- The contracts issued to Family Endeavors were awarded under contracting authorities that allow federal agencies to limit competition in certain circumstances.
- The authorities HHS used included awarding contracts based on unusual and compelling urgency and the identification of only one responsible source—in order to avoid unacceptable delays in fulfilling ORR's need to expand its bed capacity in the face of urgent circumstances.
- I understand that the OIG is currently conducting an audit of an HHS contract award to Family Endeavors. HHS recognizes and respects the OIG's authority to conduct independent audits, and we will continue to cooperate fully with the OIG.

UC - Ft. Bliss OIG Report

TALKING POINTS:

- In 2021, ORR received an unprecedented number of UC referrals during the middle of the pandemic, straining its bed capacity and also its ability quickly recruit and staff programs across the country. As ORR worked quickly to respond to this unprecedented emergency, with limited resources, it prioritized the safety and wellbeing of children at every step. Despite challenges, and lessons learned, Fort Bliss now is a model for child centered care and case management.
- ORR continues to build capacity that enhances our ability to manage emergency response efforts by expanding bed capacity, minimizing the amount of time children stay in congregate care settings, and safely placing children with vetted sponsors. Additionally, ACF has worked to increase staff training, supports and whistleblower protections to continue to provide the safest environment possible for children.
- ACF and ORR took seriously the findings of the OIG report and had already started implementing its recommendations even before it was published. Today, the reality at ICFs like Fort Bliss and Pecos is vastly different from the snapshot that the OIG report captured during the surge – bed capacity is at a record high, and time in care for children has decreased dramatically.

UC - HHS/DOL Child Labor

TALKING POINTS:

- The New York Times article demonstrates the terrible ways that employers are exploiting the economic situation that many children and families in the United States find themselves in, including children who have previously been in ORR care.
 - The previous administration left us a number of challenges to fix, and not least among them at HHS was the rebuilding of ORR and the Unaccompanied Children's Program in the face of unprecedented referrals in the midst of a global pandemic.
- We take the issue of child labor very seriously, and there are additional steps that we can take to educate children and our providers about child labor exploitation, ensure sponsors understand the hazards of child labor, and collaborate with the Department of Labor to do everything we can to reduce the likelihood that children will end up in a situation where they are exploited.
 - Of course, we always look for ways we can do better. That's why are we auditing our program to see if there's any place where we can tighten up our processes.
- Our principal responsibility is to care for unaccompanied children while they are in our custody, and then make sure we can place the child to a safe, vetted sponsor. HHS looks forward to partnering with you to advance the shared mission of protecting children and continue to strengthen the quality and depth of services we offer.

QUESTIONS:

Q: When it comes to vetting sponsors, why did HHS pair down fingerprinting and case reviews?

- First, let me start with HHS prioritizes the safety and wellbeing of every child in our care. All decisions by HHS are done with this in mind. We thoroughly vet every sponsor before placing a child in their care.
- HHS has not changed any vetting protections that would affect the safety of children in our care. In 2021, ORR received an unprecedented number of UC referrals. ORR *did not make policy changes* that cut out safety measures or accelerated processes that might *put children at risk*.
- It is particularly important to prioritize timely placement with biological parents or legal guardians. This is why we updated our process when we came into office – when it comes to placing a child with their parent (or legal guardian), **we cut through the red tape** in accordance with their parental right to be unified with their children as soon as possible. We heard from advocates and stakeholders, reviewed our process, and were able to make these improvements.

- ORR has and continues to work to keep children out of large, congregate settings without sacrificing procedures that keeps them safe.

Q: Does HHS have room for improvement?

- We continuously review our policies and procedures for ways to be more efficient and effective.
- Research shows children do much better with their families and in home settings, not government funded congregate settings.
- If a safe, vetted sponsor is available, we will not delay doing what is best for the child.

Q: How does ORR check on a child's wellbeing after they are placed with a sponsor?

- While ORR's custodial responsibilities for unaccompanied children end when the child is released from ORR care, ORR engages in a range of post-release activities and assists in supporting access to such services for children and sponsors.
- We all recognize how heartbreaking the situation is, and the challenges these children face – this calls for a whole of government response (including state government, local government, and community groups), and HHS takes our part in this continuum of care seriously.
- ORR's post-release services include assistance in connecting children and their sponsors to community-based resources suitable to their needs, and support to prevent a child from becoming a victim of trafficking.

Q: The article had recordings of you that implied you were prioritizing speed of discharges over child safety. Did the pressure of the UC surge cause HHS to sacrifice standards?

- The larger context of that quote was not captured – of course my priority and the Department's priority is to keep kids safe no matter what.
- The Department does not want children to be kept in large, congregate settings unnecessarily when a safe, vetted sponsor is available. That's both our legal and moral obligation.
 - When I made those comments, we were seeing inconsistency from week to week and wanted to improve the process while continuing to provide child-centered care for children in our custody until they were released to a thoroughly vetted sponsor.
- Last summer, there was limited space and facilities to care for children, and we needed to ensure we were being efficient – not just on one day, but every day – when it came to placing the children in our care with a safe and vetted sponsor.

Q: Recent reporting shows that there has been an increase in children being released to sponsors that are not family. Is HHS prioritizing a quick release of a child over a safer release to a family member?

- That data is not accurate. In FY 2022, 85% of children were released to their immediate or extended family. In FY 2022, 34.8% of children were released to their parents, and we continue to see an increase of unaccompanied children released to their parents. Thus far, in FY 2023, 37.3% of children have been released to their parents.

Q: Are children being sent to live with strangers?

- No. While a preexisting relationship is not required for an unaccompanied child to be released to a sponsor, ORR takes this into account when determining the suitability of the case for release and may require that the sponsor, the unaccompanied child, and the child's family, establish ongoing regular contact while the child is in ORR care prior to a release recommendations. Such releases, however, are rare.

Q: Advocates are calling for more legal services. They say that HHS is sitting on money that it could use for these services. What's your response?

- HHS has already expanded legal and post release services to historic levels and has been working to expand access to these services for all children who come through ORR care – doubling the number of children and families receiving post-release services since President Biden took office.
- We will continue to work with Congress to expand post-release services to all children by 2025 and we will continue to work with advocacy organizations to build additional legal capacity that can support our goal of providing full legal services.

Q: How, if at all, does HHS coordinate with other agencies and departments, including the Department of Labor, the Department of Justice, and others, to identify and reduce child labor exploitation, including among unaccompanied children?

- As mentioned, ORR must refer any trafficking concerns to DHS to investigate any trafficking claims.
- ORR and all its network of care providers must also refer any suspected trafficking case to the Office of Trafficking in Persons (OTIP). All cases referred to OTIP are reviewed to assess trafficking concerns and connect the minors to benefits and services.

UC - ORR/Migrant Flights

TALKING POINTS:

- This is an issue where misinformation has run rampant, and I want to set the record straight. It is our legal responsibility to provide safe, appropriate care to unaccompanied migrant children during the time they are in our custody, and that includes transportation to appropriate shelter placements and to unify with their vetted sponsors while they await immigration proceedings.
- There are no secret flights. And these flights are different and unrelated to the ones folks may have heard about on the news, such as the flights of migrant families to Martha's Vineyard. These flights to transfer UCs to their sponsors or to our network of over 200 shelter facilities in 22 states take place in accordance with the law and our responsibilities.
- Staff supervise and escort UC until they are placed in the care of another ORR facility or a vetted family member or sponsor. This has been the policy across multiple administrations since 2014. Transportation is coordinated, and clearly communicated to all appropriate parties, from a secure ORR facility to a vetted family member or sponsor or other ORR facility that is ready and awaiting the arrival of the UC. Through case management services, UC are always aware of where they are going and why.

UC - Reproductive Health

TALKING POINTS:

- ORR has a moral and legal obligation to safely and humanely care for all unaccompanied children referred to us. HHS works with our partners across the government to ensure that unaccompanied children are safe and provided – in accordance with the Flores Settlement Agreement and *Garza* – appropriate routine medical care, family planning services, access to reproductive health services, and emergency contraception and health care services.
- The Department's priority is to ensure that the populations we serve receive the reproductive care they need while following applicable legal requirements. ORR decision making is rooted in an ongoing assessment of the best interests of the child and established child welfare best practices.
- We remain committed to clearly explaining the care available and providing referrals or arranging appointments with healthcare providers which may include arranging and funding travel from states where laws may restrict care to states where necessary care is available.

QUESTIONS:

Q: What reproductive services are available to minors in ORR care?

While in ORR care and custody, UC have access to family planning services and reproductive health care. Services include: pregnancy testing, emergency contraception, and comprehensive information about and access to reproductive health services. ORR also ensures access to oral contraceptive pills that are prescribed by a healthcare provider for a medically indicated diagnosis. ORR ensures that pregnant UC receive non-directive pregnancy options counseling when necessary and that appropriate specialty care referrals are made as soon as UC is discovered to be pregnant for further evaluation and care.

Q: What policies does ORR follow in regard to abortion?

The UC program and its policies are aligned with the Flores Settlement Agreement, the Homeland Security Act, the Trafficking Victims Protection Reauthorization Act, and the ORR Policy Guide. ORR care providers are also typically state-licensed and therefore must abide by the healthcare requirements applicable in each relevant state.

Q: How does ORR protect the first amendment rights of federal staff and care provider staff who have personal/faith-based objection to abortion?

- Nothing in existing *Garza* policy prohibits ORR from providing accommodations to care providers who maintain a sincerely held religious objection to abortion; rather ORR does provide such accommodations.
- If a faith-based care provider has a religious objection to abortion, and a UC in the care of such a provider is discovered to be pregnant, ORR's field staff will personally deliver any legally required notice to the UC orally and in writing, along with other pregnancy-related information required by ORR policy.

- Faith-based providers are critical partners for our mission. ORR operates 102 different faith-based providers in at least 18 states.

Q: What if UC in care does not want an abortion? What care is provided to them?

- ORR is required to provide pregnant UC non-directive options counseling. UC are notified that neither the federal government, nor care providers, may obstruct or interfere with UC accessing counseling about all the options they have regarding their pregnancy.
- UC in ORR care can decide whether to continue their pregnancy or terminate the pregnancy.

Q: How many pregnant UCs have given birth (and kept) their babies? How many UCs have requested abortion since the passing of the Dobbs decision? How many abortions does ORR pay for each year?

ORR does not disclose this information to protect children's medical and health privacy, especially given that this is a very small number.

Q: What about the Hyde Amendment? How are federal funds being used to provide abortions for UC?

Nothing in the ORR Garza policy supersedes applicable Federal appropriations restrictions such as those outlined in the Hyde Amendment.

Q: Does the government pay for transportation of UC across state lines to access abortion services? Is this true for Hyde Amendment and non-Hyde Amendment abortions?

ORR regularly facilitates access to medical services for UC, including transporting UC across state lines, when necessary. The care provider is responsible for transporting the UC to medical appointments, including access to reproductive health care across state lines. Where a religious exemption is in place, ORR staff may assist with the transportation of the UC to seek abortion services.

Q: Does the government pay for lodging, translation, and other ancillary services, in the course of facilitating access to abortion services? Is this true for Hyde Amendment and non-Hyde Amendment abortions?

Yes, the government may fund lodging, translation, and other ancillary services in the course of facilitating access to abortion, regardless of whether the pregnancy meets the Hyde Amendment specifications or not. Care providers and child advocates may receive donations to help pay for some of these expenses on an as-needed basis.

Q: Does ORR prohibit access to abortion past a certain gestation ("late-term pregnancy")?

ORR federal staff and care provider staff will assist in facilitating an abortion request by a UC, based on the available in consultation with DHUC, in compliance with *Garza* requirements and the Hyde Amendment. The time limit for an abortion procedure prescribed to the UC is in the purview of the medical provider and the UC and is not the purview of ORR.

UC - Sponsor Vetting/Post-Release Services

TALKING POINTS:

- Safety and well-being are at the forefront of every decision we make at HHS. Child welfare best practices are clear that the best place for a child is in a community with family and not in large congregate care settings. Once we identify a safe, vetted sponsor, who has undergone a robust screening process, we have a responsibility to place the child as quickly as possible.
- We also understand the importance of providing children and sponsors with the tools and resources necessary to help a child succeed post-release and develop permanent connections for support and resilience as a child transition into a new community.
- HHS has already expanded legal and post release services to historic levels and has been working to expand access to these services for all children who come through ORR care – doubling the number of children and families receiving post-release services since President Biden took office.
- HHS will continue to work with Congress to ensure we have the funding to build on this expansion of post-release services with the goal of serving all children within the next two years. It will also continue to evaluate pathways to strengthen

QUESTIONS:

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Q: How does ORR check on a child's wellbeing after they are placed with a sponsor?

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- We all recognize how heartbreaking the situation is, and the challenges these children face – this calls for a whole of government response (including state government, local government, and community groups), and HHS takes our part in this continuum of care seriously.
- ORR's post-release services include assistance in connecting children and their sponsors to community-based resources suitable to their needs, and support to prevent a child from becoming a victim of trafficking.

Q: Recent reporting shows that there has been an increase in children being released to sponsors that are not family. Is HHS prioritizing a quick release of a child over a safer release to a family member?

- That data is not accurate. In FY 2022, 85% of children were released to their immediate or extended family. In FY 2022, 34.8% of children were released to their parents, and we continue to see an increase of unaccompanied children released to their parents. Thus far, in FY 2023, 37.3% of children have been released to their parents.

Q: Are children being sent to live with strangers?

- No. While a preexisting relationship is not required for an unaccompanied child to be released to a sponsor, ORR takes this into account when determining the suitability of the case for release and may require that the sponsor, the unaccompanied child, and the child's family, establish ongoing regular contact while the child is in ORR care prior to a release recommendations. Such releases, however, are rare.

Q: What exactly is the process for vetting sponsors?

- The process includes a proactive search by the care provider for a potential sponsor; a written sponsor application; interviews; required documentation establishing sponsor identity, address, relationship to the child, and other supporting documentation; background checks; and home studies as required by law and in ORR's discretion consistent with its policies.
- ORR thoroughly screens sponsors through tools that may include public records checks, sex offender registry checks, and fingerprinting.

Q: Why would numerous unaccompanied children be released to the same address?

There might be various reasons why several children are released to sponsors at the same address including a large apartment complex or other address with multiple units. ORR has systems in place that alert users when sponsors are concurrently sponsoring other

children or have sponsored other children in the past. If ORR records show that multiple children are being released to the same address, ORR might conduct additional checks, such as requiring home studies before releasing other UC to those locations.

UC - Transgender Care

TALKING POINTS:

- ORR has a moral and legal obligation to safely and humanely care for all unaccompanied children referred to us. That means that *all* children and youth in ORR care are entitled to human rights protections and freedom from discrimination and abuse, no matter their gender or sexuality.
- Care providers must ensure that LGBTQI children are fairly treated and served and are not discriminated against during their time in ORR care. That means in part that they must maintain privacy and confidentiality of information concerning sexual orientation and gender identity. They need to use correct names and pronouns in accordance with the youth's gender identity. They must house LGBTQI youth according to an assessment of the youth's gender identity and housing preference, health and safety needs, and State and local licensing standards.
- While we have a guide for provider obligations with respect to LGBTQI children and youth in ORR care, ORR does not currently have any other policy on access to gender-affirming care. Faith-based providers are critical partners for our mission. ORR does not have specific policy concerning faith-based grantees and care for transgender UCs. This is a new policy area for ORR, and we continue to study the issue for policy development.

QUESTIONS:

Q: Does ORR provide gender-altering healthcare to UC at their request? Are there examples of this happening?

- UC Policy Guide 3.5 outlines care provider obligations with respect to LGBTQI children and youth in ORR care. The ORR UC Program does not currently have any other policy on access to gender-affirming care.

Q: Does ORR allow for male children to reside in female residential areas and utilize female restrooms just because they say so?

- To provide the least restrictive placement suitable for each child and ensure the safety and wellbeing of children in care, ORR considers all available information when making placement decisions, including the child's identity documents, physical anatomy, and self-identification of their gender and safety needs when determining the child's housing and service allocation.
- Care providers must offer an individualized assessment to determine whether additional or alternate restroom accommodations should be provided. UC are always supervised and ORR's priority is the safety of all children in its care.

Q: What is a woman?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- Support youth and families; HHS commitment to advance safety and support for LGBTI+ youth. Access to gender affirming care, when medically necessary can be lifesaving.
 - Ensuring such access is the law.

Q: How many genders are there?

- I am focused on making sure people have health care, period. And part of that is following the law, and making sure people can receive care without stigma, barriers and discrimination.
- At HHS, we are committed to advancing health equity for people of all genders. Health equity is defined by HHS Healthy People 2030 as the “attainment of the highest quality of health for all people.” We work toward that goal every day.

Q: Does HHS support irreversible genital surgeries on children?

- Transgender medicine is a well-established but complex field. HHS supports the current well-established standards of care, established by the top medical professionals and scientists in the field. These standards of care are supported by the vast majority of major medical associations.

Q: What other requirements are providers supposed to adhere to in regard to LGBTQI children?

- They must maintain privacy and confidentiality of information concerning sexual orientation and gender identity.
- They need to use correct names and pronouns in accordance with the youth's gender identity. They must house LGBTQI youth according to an assessment of the youth's gender identity and housing preference, health and safety needs, and State and local licensing standards.
- They must offer an individualized assessment to determine whether additional or alternate restroom accommodations should be provided.
- They must allow LGBTQI youth to dress and express themselves according to their gender identity.
- They must allow LGBTQI youth to choose the gender of staff to conduct a pat-down search if one is necessary.

UC - Violent/Criminal Former UCs

TALKING POINTS:

- This administration takes all cases of violent crime seriously, no matter the immigration status of the alleged criminal, or whether the individual was formerly in the custody of ORR care. While we remain committed to working with Congress to comprehensively fix the problems of a long-broken immigration system, ORR is not an immigration enforcement entity. It is ORR's legal responsibility to provide a safe environment for all children in its care.
- Since 2019, ORR has made significant improvements to assess and address its network capacity to better serve the needs of children with mental health and behavioral issues, including seeking and coordinating increased mental health and treatment services for shelter cases needing specialized placement.
- While ORR's custodial responsibilities for unaccompanied children end when the child is released from ORR care, ORR engages in a range of post-release activities and assists in supporting access to such services for children and sponsors. We have been building capacity to increase post release services and we are on track this year to serve more than 50% of children released from our care.
 - HHS will continue to work with Congress to ensure we have the funding to build on this expansion of post-release services with the goal of serving all children within the next two years.

QUESTIONS:

Q: The Biden Administration's open-border policies created vulnerabilities that criminals and gang members exploit. What is the Department doing

Refer to CBP and DHS for specific questions on immigration policy. Again, ORR is not an immigration enforcement or law enforcement entity.

Q: What is HHS doing to verify whether UCs referred to their care are members of MS-13 or other violent gangs?

- HHS is required to ensure the safety and care of all unaccompanied children in ORR custody. Pursuant to the Trafficking Victims Protection Reauthorization Act, ORR is required to provide safe and secure placement for children. In addition, the *Flores* Settlement Agreement also outlines factors HHS must consider when ORR is making placement determinations, such as screenings for self-harm, harm to others, and flight risk. These requirements are reflected in ORR's UC Program Policy Guide (Section 1.2.4).
- HHS does not have the authority to conduct background checks on unaccompanied children. Prior to the Department of Homeland Security referring children to ORR custody, DHS fingerprints all children over the age of 14, and if there is criminal history based on those biometrics, these are reported to ORR as obligated under the 2021 HHS

and DHS Memorandum of Agreement. This MOA creates an affirmative obligation for DHS to provide the criminal history, gang affiliation, court docs, etc. for an unaccompanied child upon their referral to HHS. If made aware of additional DHS documents or court records, ORR will also seek these records.

Q: There have been reports that there has been a rise in missing unaccompanied children across the country. Is ORR tracking these children after release?

- Though ORR does not have custody of children after they are discharged, ORR provides safety and wellbeing calls to all children, and post-release services and legal representation to many children. ORR cannot compel former unaccompanied children or sponsors to respond to inquiries or participate in these services. There are many reasons why discharged unaccompanied children, who often live in mixed-immigration-status families, may not want to be contacted by the U.S. government.

World Health Organization (WHO)

TALKING POINTS:

- We know that the challenges we face won't be solved by one leader or one country alone, but by the world coming together and fighting for what's right.
- The WHO is an essential organization; they are the only international organization with the mandate and convening power to bring together Ministries of Health and health experts across 194 countries.
- I strongly support the ongoing efforts to strengthen the WHO and make it more agile, transparent, efficient, and accountable.

QUESTIONS:

Q: Do you commit to voting against any reform in the Pandemic Accord or to the IHR that would violate the United States' sovereignty?

- The United States will not support any measure at the World Health Organization, including in these negotiations, that in any way undermines our sovereignty or security.
- Any accord resulting from these negotiations would be designed to increase the transparency and effectiveness of cooperation among nations during global pandemics and would in no way empower the WHO or any other international body to impose, direct, or oversee national actions.
- It will not compromise the ability of American citizens to make their own health care decisions.

Q: What steps will you take to ensure WHO adequately responds to allegations of widespread sexual abuse and exploitation?

- There must be zero tolerance for sexual exploitation and abuse at the WHO.

- HHS, State, and USAID have been working closely with the WHO as they respond to sexual exploitation and abuse allegations and work to build stronger systems to prevent and address this in the future.
- The WHO has made improvements and laid out a Management Response Plan with next steps to continue progress, but our pressure on these issues must continue to be a top priority.

Q: Do you support obligating the United States via international agreement to provide reproductive health services, including abortion, as essential health care during a pandemic?

I will comply with all legislative restrictions on foreign assistance related to abortion, including restrictions against advocating for or against abortion in multilateral fora.

Q: It was recently reported that WHO was abandoning its investigation into the origins of the coronavirus. Do you think now is the time for international organizations like WHO to give in to China's obstruction and give up on this investigation?

- No. For more than two years, China has blocked international investigators and members of the global public health community from accessing information related to COVID-19 origins. This is unacceptable – and we must not let this prevent us from getting answers.
- If we're going to get to the bottom of this question, we need critical information about the origins of this pandemic that exists in the People's Republic of China.
- International investigators and members of the global public health community should have access to it.

Workforce – Head Start / Child Care

TALKING POINTS:

- Head Start cannot fulfill its mission to serve children and families from vulnerable communities without a robust, well supported workforce.
- Head Start preschool teachers earn drastically less than kindergarten teachers with the same credentials, which limits a program's ability to recruit and retain staff.
- The budget would provide a much-needed investment to stabilize the workforce, including \$440 million for a cost-of-living adjustment for Head Start wages to keep pace with inflation. The budget also directs \$575 million to improve compensation for Head Start workers.
- We continue to explore how federal policy can better support the Head Start and child care workforce, as well as how to leverage opportunities available from partners at the local, state, and federal levels.

Background

The budget requests \$13.1 billion, an increase of \$1.1 billion above FY 2023 enacted, to provide comprehensive early learning and development services to infants, toddlers, and preschool-aged children from economically disadvantaged families. This funding includes \$440 million for a cost-of-living adjustment for Head Start wages to keep pace with inflation. The budget also directs \$575 million to improve compensation for Head Start workers. This investment reflects the Administration's priority of building and retaining a strong early childhood education workforce. The Administration continues to invest \$100 million in Early Head Start-Child Care Partnerships. The partnership's funding provides comprehensive and continuous Early Head Start and child care services to low-income families with infants and toddlers. These investments will serve an estimated 813,573 children and families through nearly 1,600 local agencies in states, territories, and tribes across the United States.

Workforce - Health Care

TALKING POINTS:

- The need for a strong and robust healthcare workforce could not have been more apparent than during the height of the COVID-19 pandemic.
- We must continue to invest robustly in training, ongoing education, and mental well-being of our health care workforce.
- HHS has invested **hundreds of millions of dollars** in the health care workforce over the past year.
 - Over the next 5 years, we will create **1,000 new Graduate Medical Education (GME) slots**. The first 200 GME slots were created at the beginning of 2023. Specifically focused on primary and mental health care providers.
 - We've invested **\$103 million** to provide resources to support health care workers and **prevent burnout**.
 - The National Health Service Corps is at its largest field strength, over **20,000 members**, serving at more than **9,000 community health care centers** seeing more than **21 million patients**.
 - Awarded **\$225 million** to train **13,000 community health workers** to strengthen the public health care workforce to prepare for future public health threats.
- The President's Budget for FY 2024 seeks to extend and expand funding for these programs to ensure that recent gains and funding capacity on these programs is not lost.

QUESTIONS:

Q: How does the Budget increase and strengthen the health workforce in response to health workforce shortages?

- The FY 24 Budget has several initiatives that will grow, diversify, and promote the well-being of the health workforce. The Budget proposes to:
 - Extend and increase mandatory funding for National Health Service Corps and Teaching Health Center Graduate Medical Education for 3 years through FY 2026.
 - Provide scholarships and loan repayment to clinicians in return for practicing in underserved areas and support over 20,000 providers (National Health Service Corps, \$965.6 million, an increase of \$547.7 million).
 - Funds over 1,400 primary care physicians and dental residents in community-based training (Teaching Health Center Graduate Medical Education, \$157 million, an increase of \$37.7 million).
 - Train Certified Nurse Midwives and to expand and modernize nursing education programs by increasing nurse faculty (\$349.9 Million, an increase of \$49.5 million, for the nursing workforce).
 - Train 18,000 more mental health and SUD providers (\$387.4 million, an increase of \$190.3 million, for Behavioral Health Workforce Development Programs).

- Seed new approaches with a new Health Care Innovation Workforce program to grow the health care workforce and address shortages (\$27.5 million).
- Expand the diversity of the health professions workforce (\$110.2 million, an increase of \$10.7 million).
- Support the behavioral health, and well-being of health care providers (\$25 million).

Q: If the NHSC received all of the funding requested in the President's Budget, will it eliminate workforce shortages? What would you need to close out the primary care shortages?

- The Budget would sustain and expand the record number of providers currently providing care or getting trained to serve in underserved and rural communities.
- Eliminating larger provider shortages would require a broader approach to build the pipeline, expand training capacity, and provide incentives for providers to go into communities with shortages, as well as increasing the number of other health care providers that comprise the care team, such as nurses, physician assistants, medical assistants, lab technicians and others.

Q: What are the consequences of not extending mandatory funding for the Teaching Health Center Graduate Medical Education Program?

- If funding is not received, hundreds of medical residents currently being trained in community-based settings could face interruption or termination of their residency programs.
- Without renewed funding, Teaching Health Centers may reduce the number of available training slots and some programs may close entirely.

Workforce - Mental Health

TALKING POINTS:

- HHS is committed to strengthening and expanding the workforce to respond to the mental health and substance use disorder crisis.
- We've been hard at work – working with Congress we've created new Graduate Medical Education slots, invested in resources to prevent burnout, funded training of community health workers, and more.
- But much more can and should be done. That is why the budget invests in the **behavioral health workforce** by supporting an estimated 27,000 total mental health and substance use disorder trainees and providers.
- Specifically, the budget proposes \$387 million for Behavioral Health Training Programs, an increase of +\$190 million, to grow the number of behavioral health professionals through training approximately 18,000 behavioral health providers; such as psychiatrists, psychologists, clinical social workers, marriage and family therapists, counselors, and peer support specialists.

QUESTIONS:

Q: What has HHS done to expand the mental health workforce?

- Working with Congress, HHS has invested **hundreds of millions of dollars** in the health care workforce over the past year.
 - Over the next 5 years, we will create **1,000 new Graduate Medical Education (GME) slots**. The first 200 GME slots were created at the beginning of 2023. Specifically focused on primary and mental health care providers. An additional 200 GME slots were added by CAA 2023, with 100 dedicated to psychiatry or psychiatry subspecialty residency positions.
 - We've invested **\$103 million** to provide resources to support health care workers and **prevent burnout**.
 - The National Health Service Corps is at its largest field strength, over **20,000 members**, serving at more than **9,000 community health care centers** seeing more than **21 million patients**.
 - Awarded **\$225 million** to train **13,000 community health workers** to strengthen the public health care workforce to prepare for future public health threats.
 - Next year, Medicare will finally **provide payment to care provided by therapists and Licensed Professional Counselors**.

Q: What else do you think needs to be done to expand the workforce?

- The FY 24 Budget has several initiatives that will grow, diversify, and strengthen the mental health workforce. The Budget proposes to:
 - Train 18,000 more mental health and SUD providers (\$387.4 million, an increase of \$190.3 million, for Behavioral Health Workforce Development Programs).

- Provide scholarships and loan repayment to clinicians in return for practicing in underserved areas and support over 20,000 providers (National Health Service Corps, \$965.6 million, an increase of \$547.7 million). The NHSC supports primary care medical, dental, and behavioral health providers through scholarships and loan repayment programs.
- Allocate \$37 million for the Minority Fellowship Program (MFP) to almost double the number of fellows in FY 2024. The budget also proposes to add a service requirement to ensure participants are supporting communities in need, as well as to add addiction medicine, and sexual and gender minority populations as participants in the program. .
- Allow Medicare to designate additional professionals such as clinical social workers, peer support workers, and certified addiction counselors to furnish behavioral health services within their applicable state licensure or scope of practice – the proposal builds CAA 2023's coverage for behavioral health services furnished by marriage and family therapists and mental health counselors.