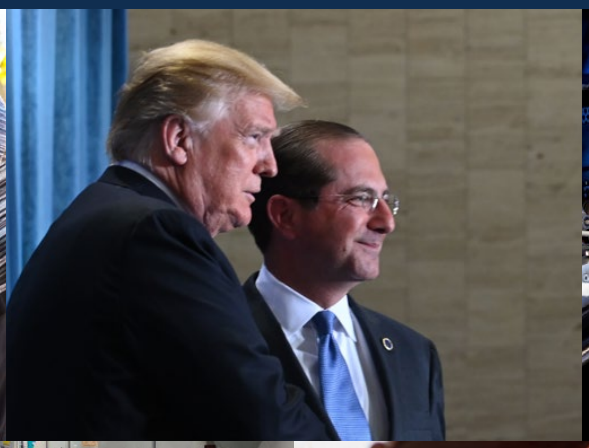
U.S. Department of Health and Human Services

2018 ANNUAL REPORT



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Introduction

THE YEAR 2018 MARKED tremendous accomplishments by the men and women of the Department of Health and Human Services (HHS). It was the privilege of a lifetime to see all of the progress made by the dedicated team since I had the honor of arriving at the department—and, as of January 25, it's been just one year!

The HHS team devoted its talents to advancing the department's mission of improving the health and well-being of the American people, by implementing dozens of innovative ideas, policy changes, and new research projects. The department is united by a strategic vision: a country where our HHS programs, and America's healthcare, human services, public health, and biomedical science institutions, work better for the people we serve.

This work is organized around the five goals laid out in our strategic plan, which was updated in Fiscal Year 2018:

1. Reform, strengthen, and modernize the nation's healthcare system.
2. Protect the health of Americans where they live, learn, work, and play.
3. Strengthen the economic and social well-being of Americans across the lifespan.
4. Foster sound, sustained advances in the sciences.
5. Promote effective and efficient management and stewardship.

Delivering on these goals requires not just innovating and executing among our team at HHS and within our own walls. Even as a more than $1 trillion department, with more than 80,000 employees, we would do well to recognize how many partners are necessary to create sustained and significant improvements for the people we serve.

We have lofty goals, including four priorities I have laid out: lowering the price of prescription drugs, defeating the opioid epidemic, reforming how Americans finance their healthcare, and transforming our healthcare system into one that pays for value. But we also have to continue developing America's biomedical research enterprise, improve the quality of care offered in tribal health facilities, promote work and independence in our human services programs, fight key public health battles such as the rising wave of youth e-cigarette use, and so much more.

Winning these battles will require not just innovative use of the powers and resources of government, but also enlisting all other stakeholders, whose buy-in will be necessary to create sustained and significant improvements for the people we serve.

As we plan for 2019, I have great confidence that the HHS team will take this message to heart and continue delivering historic results for the American people.

Alex M. Azar II
Secretary of Health and Human Services

Executive Summary

THIS ANNUAL REPORT is organized into five sections corresponding to the HHS department strategic goals as laid out in our 2018-2022 strategic plan.

Goal 1: Reform, Strengthen, and Modernize the Nation's Health Care System

HHS endeavors to improve the quality and reduce the cost of healthcare Americans receive through reforming the programs the department runs, advancing the direct care provided in our programs, and ensuring government incentives do not prevent patients and providers from working together to drive value. Accomplishments in this section include:

- **Releasing and implementing** the *American Patients First* drug pricing blueprint.
- Empowering pharmacists to always be able to tell patients what the **least expensive option** for their medicine is through legislation banning pharmacy gag clauses.
- **Historic approvals from FDA**, with a record 59 novel drugs or biological products approved and a record number of generic drug approvals for the second straight fiscal year.
- **For the first time since their inception**, the average premium on a benchmark plan on HealthCare.gov was lowered by about 1.5 percent.
- **Expanding Association Health Plans**, making it easier for employers to join together to offer more affordable coverage to their workers.
- Finalizing a rule expanding availability of short-term, limited-duration insurance, which tend to be nearly **50 percent cheaper** than plans under the ACA.

Goal 2: Protect the Health and Well-Being of Americans Where They Live, Learn, Work, and Play

HHS's work to protect the health of Americans extends from addressing the most pressing public health threats in our local communities, including the opioid crisis, HIV, and other infectious diseases, all the way to addressing and preventing health threats around the world. Covered in this section are accomplishments including:

- **Awarding $1 billion** through the State Opioid Response grant program to fight the epidemic.
- **Nearly doubling NIH funding for research into pain and addiction**, to $1.1 billion, as part of the HEAL Initiative.
- Using science to update the **comprehensive strategic framework** for tackling the opioid crisis.
- Deployed more than **1,050 U.S. Public Health Commissioned Corps officers and** other **HHS staff** throughout 2018 to respond to national emergencies, natural disasters, and other public health crises and missions.
- **Led the launch** of the first ever National Biodefense Strategy.
- **First-ever Humanitarian Service Medal awarded** to the Public Health Service Commissioned Corps and other HHS staff for a large deployment.

Goal 3: Strengthen the Economic and Social Well-Being of Americans across the Lifespan

From delivering health visits for new moms and supporting Early Start locations across

America, to supporting aging and disability networks that help older Americans live in their communities longer than ever before, HHS plays a vital role in providing human services to vulnerable Americans at all stages of life. This section covers items such as:

- CMS **approving first-ever state demonstrations incentivizing work and community engagement** among a large population spanning five states.
- Continuing to protect conscience and life in healthcare settings by **launching a conscience division within the HHS Office of Civil Rights.**
- Issuing a final rule **providing regulatory relief** to employers like the Little Sisters of the Poor, protecting conscience rights.
- **Working with the VA to expand the Veteran-Directed Care program**, which uses aging and disability networks to support veterans living in their communities rather than in nursing homes.

Goal 4: Foster Sound, Sustained Advances in the Sciences

HHS is proud to be home not just to many of the world's preeminent individual scientists, public health experts, and clinicians, but also the world's finest scientific institutions: the largest single source of biomedical research funding in the world in NIH, the world's premier epidemiological institution in CDC, and the world's gold-standard food and drug safety agency in FDA. This section covers our work including:

- Creating the **unprecedented *All of Us* long-term research study** with the National Institutes of Health, in which 150,00 people have already signed up to participate.
- Advancing the **Cancer Moonshot with more than $300 million in 2018 research investments**.
- **Launching an Accelerating Medicines** Partnership focusing on identifying and validating promising markers of Parkinson's Disease.
- Fostering collaboration between NIH and the VA **to boost veterans' access to cancer clinical trials**.

Goal 5: Promote Effective and Efficient Management and Stewardship

In 2018, HHS took major steps forward in departmental management, from reforms of the regulatory burdens it places on healthcare and human services partners to developing new tools for improving departmental and financial management. Included in this section:

- Charging over 600 individuals in fraud that cost $2 billion in losses to Medicare and Medicaid as part of the **largest National Healthcare Fraud Takedown Day in history**.
- Reducing the present-value economic burden of HHS regulations by **$12.5 billion—more than half of the deregulatory burden reduction for the entire administration in 2018**.
- Ranked as the **second best** large federal agency to work at for the second straight year.
- Cutting improper payments in Medicare and Medicaid by **$4.6 billion** from 2017 to 2018.

GOAL 1

Reform, Strengthen, and Modernize the Nation's Healthcare System

HHS ENDEAVORS TO IMPROVE the quality and reduce the cost of healthcare Americans receive through reforming the programs the department runs, advancing the direct care provided in our programs, and ensuring government incentives are not distorting ways that the market can work to improve the quality of care. Three of the four priorities Secretary Azar has laid down for the department fall under this strategic goal: lowering prescription drug prices, driving toward a value-based healthcare system, and reforming the individual market for health insurance.

Lowering Drug Prices

In May 2018, President Trump and Secretary Azar published *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, which laid out dozens of possible ideas for accomplishing its goals. It laid out four strategies:

- Boosting competition
- Improving negotiation
- Creating incentives for lower list prices
- Lowering out-of-pocket costs

The blueprint also identified foreign freeriding off of American investment in innovation as a particular issue that can be tackled from a health-policy and trade perspective.

From the release of the blueprint through the end of 2018, more than a dozen drug companies cut drug prices, rolled back planned increases, or froze prices for the rest of 2018. During the same time period, companies took 57 percent fewer price increases than they did during the same period a year earlier. For the first time in almost 50 years, in 2018, the official federal measure of inflation for consumer drug costs was negative.

Boosting Competition

Record results on generic drugs: The Food and Drug Administration (FDA) set a record for total generic drug approvals in Fiscal Year 2018, surpassing the record it had set in 2017. In October 2018, FDA also set a record for the number of approvals. In total, more than 2,000 generic drugs have been approved under the Trump administration, which the Council of Economic Advisors found have saved consumers $26 billion already.

While managing this record workload, FDA exceeded the Generic Drug User Fee Amendments (GDUFA) performance goal of completing action on more than 90 percent of ANDAs, amendments and supplements.

Launching a Biosimilars Action Plan: In July 2018, FDA launched a plan to expand access to and use of biosimilars: more affordable alternatives to expensive biologic medicines, which represent almost 40 percent of all prescription drug spending. The plan aims to 1) improve the efficiency of the development and approval process; 2) maximize scientific and regulatory clarity for developers; 3) develop effective communications to improve understanding of biosimilars among patients, clinicians, and payers; and 4) support market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition.

Record novel drug approvals: In 2018, FDA approved 59 novel drugs and biological products, a calendar-year record. Some of these products are innovative new products that never before have been used in clinical practice. Others are the same as, or related to, previously approved products, and they will compete with those products in the marketplace.

President Donald J. Trump and Secretary Alex Azar unveil the "American Patients First" blueprint to lower drug prices and reduce out-of-pocket costs.

Expanding access to nonprescription drugs: Nonprescription drugs can offer more affordable or convenient options for patients. In July 2018, FDA published a new draft guidance that applies to drugs that have not, historically, been available for use without a prescription, outlining two innovative approaches for demonstrating safety and effectiveness necessary for over-the-counter (OTC) approval. These approaches could involve the use of technology, such as mobile apps or other tools, reflecting FDA's efforts to leveraging technology to promote public health and clinical care.

More FDA process advances: FDA also successfully implemented an unprecedented concept of operations that integrated facility inspections and evaluations, and implemented the GDUFA II transparency commitment one year early, by issuing 129 final facility classification letters prior to October 1, 2018.

Improving Negotiation

Bringing more negotiation to Medicare Part D: Since its passage in 2003, Medicare Part D has, in many ways, successfully held down costs and driven competition in drug markets. However, the program has not permitted plans to adopt the latest negotiating tools used by insurers in the commercial market to drive down drug costs. Since the launch of the blueprint, a number of steps have been taken to provide plans with new negotiating tools. For Plan Year 2020, for instance, the Center for Medicare & Medicaid Services (CMS) proposed giving plans access to tools to negotiate bigger discounts for some of the most expensive drugs in Part D, where private plans often obtain 20 to 30 percent discounts.

New negotiating tools for Medicare Advantage: In 2018, CMS gave Medicare Advantage plans new tools to negotiate lower prices for expensive Part B drugs, a $12 billion drug market. These same tools often generate savings of 15 to 20 percent in the private market, which could be passed on to the 20 million seniors enrolled in Medicare Advantage plans as soon as next year. Already for 2019, at least one major insurer is using these tools to have patients first use a much-lower-cost biosimilar, with lower out-of-pocket costs.

First-ever state plan amendments for state value-based purchasing arrangements: CMS approved first-ever, innovative state-plan amendments in Michigan and Oklahoma to allow their Medicaid programs to enter contracts involving value-based purchasing arrangements with drug companies, which can produce extra rebates for the states based on whether certain clinical outcomes occur.

Incentives for Lower List Prices

First ever proposal for requiring drug price transparency for consumers: In 2018, HHS proposed the first-ever requirement that the list price of a drug's usual course of therapy or a

30-day supply be disclosed to patients in television advertising.

Providing this information will offer a historic step forward for drug-price transparency because many patients either pay list price or pay prices calculated based on list price: 47 percent of Americans have high-deductible health plans, under which they often pay based on the list price of a drug until their insurance kicks in, and all seniors on Medicare Part D face coinsurance, calculated as a share of list price, if they take certain expensive drugs. In total, according to **one survey**, almost half of patients' out-of-pocket spending on drugs in employer insurance is attributable to coinsurance or deductible spending. The list prices of the most commonly advertised drugs are substantial: The ten most commonly advertised drugs have list prices ranging from $535 to $11,000 per month or usual course of therapy.

Providing real-time cost and price information: In a Part D proposed rule for Plan Year 2020, CMS proposed that all Part D plans be required to support tools that allow prescribers access to real-time prescription-benefit information within their existing electronic prescribing systems.

Prescribers and patients can use these tools to understand the prescription-drug options they may have, with information provided about the out-of-pocket cost the patient will face for a given drug. These options are available in the commercial-insurance market and represent a significant step toward helping patients understand how much a drug is going to cost them before it is prescribed to them.

New transparency around price increases: Within weeks after the blueprint's release, CMS made significant changes to its Drug Pricing Dashboard, highlighting the individual drugs with the highest price increases in Medicaid, Medicare Part B, and Medicare Part D, and, for the first time, the manufacturers responsible.

Lowering Out-of-Pocket Costs

Realigning Medicare reimbursement to save for taxpayers and patients: CMS proposed or implemented a number of changes in 2018 to reduce what patients pay in out of cost for expensive drugs in Medicare Part B fee-for-service, including reductions to reimbursement for drugs under the 340B drug discount program, calculated to save patients $320 million in 2018 alone.

Banning "gag clauses": According to **one study**, 23 percent of patients are paying more in co-pays at the pharmacy for drugs than they would if they paid in cash. Within a week of the blueprint's release, CMS put Medicare Part D plans on notice that it was unacceptable to impose pharmacy "gag clauses," which can prevent pharmacists from working with patients to identify the lowest-cost way to obtain their drugs. Then, in the fall of 2018, President Trump signed **two pieces of legislation** banning these gag clauses, ensuring pharmacists

President Donald J. Trump displays his signature after signing S. 2553- the Know the Lowest Price Act and S.2554- the Patients Right to Know Act.

can always help Americans get the best deal on the drugs they need.

Reinforcing tools to encourage adoption of low-cost generics: **CMS reminded Part D plans** of tools they have to encourage patients to use low-cost generics, which carry lower out-of-pocket costs, instead of brand-drug alternatives. The design of Part D has allowed generic drugs to gain a more than 90 percent market share, which has helped hold down patient out-of-pocket costs, but plans have now been urged to use their existing tools to drive even more adoption of generics.

Addressing Foreign Freeriding

Put forth first-ever international reference-pricing model: In October, President Trump visited the HHS headquarters in Washington to announce that the administration was putting forth the first ever proposal to secure for Americans a share of discounts that other wealthy countries receive on some of the most costly drugs in Medicare. The model, the International Pricing Index, would take what Medicare pays for a set of drugs from 80 percent more than other countries pay to just 26 percent more over five years, saving patients and Medicare an estimated $17 billion. In addition, putting forth the model has changed the dynamics around other countries' drug-pricing negotiations already, by setting out the principle that any discounts drug companies give to other countries may be reflected in the prices those companies receive in the United States as well.

Fought for drug affordability and innovation incentives in trade negotiations: Through the Office of Global Affairs, HHS contributed to the successful renegotiation of the United States-Mexico-Canada Agreement (USMCA), including through the strengthening of requirements for science-based and transparent policies, as well as increased protections for pharmaceutical innovations. HHS also influenced outcomes in global discussions on pharmaceutical drug pricing and innovation policies at multilateral institutions such as the OECD and the World Health Organization, and through bilateral outreach to key partners including India and the EU.

Driving Toward a Value-Based Healthcare System

In 2018, Secretary Azar chose as one of his four priorities the transformation of America's healthcare system into one that pays for value. Secretary Azar and Adam Boehler, director of the Center for Medicare and Medicaid Innovation (CMMI) and senior advisor for value-based transformation, have laid out a four-pronged vision for this transformation, relying on patients and individuals to drive value:

- Patients as empowered consumers
- Providers as accountable navigators
- Paying for outcomes
- Preventing disease before it occurs or progresses

Patients as Empowered Consumers

New transparency around hospital prices: For the first time ever, as of January 1, 2019, hospitals are required to post their standard set of charges online in a machine-readable format—a first step toward greater price transparency that **one healthcare leader said** "could be a game-changer for health care."

Advancing health IT: In 2018, the Trump administration took a number of steps toward ensuring that patients have access to and control over their own health data and records.

- The administration launched the government-wide MyHealthEData initiative, specifically focused on empowering consumers through control of their own health data.
- CMS launched Blue Button 2.0, an update of a largely unused system that gives seniors access to their Medicare records. Blue Button 2.0 enables seniors to request disclosure of their Medicare information to application developers, so the information can be used to improve care and increase positive health outcomes. So far, over 1,300 developers are working on new apps to serve seniors.
- The Office of the National Coordinator for Health IT (ONC) issued **a draft of the Trusted Exchange Framework,** which outlined a set of principles, terms, and conditions to support the development of a full Common Agreement that would enable the exchange of health IT data among disparate networks.
- ONC issued the **ONC Guide to Getting and Using your Health Records**, which provides information to patients and consumers about how to get, check and use their health information, which supports the MyHealthEData initiative by helping patients access their own records.

Secretary Azar talks with CMMI Director and Senior Advisor for Value-Based Transformation and Innovation Adam Boehler.

- The Health Resources and Services Administration (HRSA) piloted a modernized approach for Uniform Data System reporting capabilities with six health centers, which demonstrated an 88 percent reduction in administrative burden and will serve as a prototype for all health centers in 2019.

New benefits in Medicare Advantage: CMS provided Medicare Advantage plans with flexibility to pay for a greater array of benefits that can support health. These can include transportation, in-home health visits, home-delivered meals, home modifications, and more. Two of the largest insurance plans, in Florida and Texas, will pay for up to 42 hours of help from a home health aide for people who need help at home to provide their regular caregiver with a respite.

New shopping tools for seniors: To help determine whether Medicare Advantage may work for them, and which plans may be best, CMS improved the online Coverage Wizard to help seniors choose the plan that's right for them, added a new cost estimator tool, and added webchat to help seniors find easier assistance.

Expanding use of telehealth: CMS expanded the reimbursement options for telehealth within Medicare and Medicare Advantage, while HRSA also enhanced technical and policy guidance to support health centers' use of telehealth. In 2018, HRSA announced that, in the previous year, the number of health centers using telehealth to provide services had increased by 15 percent.

Improving reporting of patient-reported outcomes: The Agency for Health Research and Quality (AHRQ) launched the **Step Up App Challenge**, a three-phase competition to address the need for greater use of standardized patient-reported outcomes (PRO) data in clinical care and research. Some digital tools collect these data, but they are not widely used due to problems with integrating them in practice workflow and patients' discomfort with using such tools. This competition will result in a user-friendly app that can improve collecting PRO data and, as a result, increase the patients' voice in their care.

Making more health-quality data available: **AHRQ's Comparative Health Systems Performance (CHSP) Initiative** released **new data files** in October 2018 with characteristics of 626 U.S. health systems. These files complement existing AHRQ databases and contribute to AHRQ's effort to build a data insight platform that captures a 360-degree view of the U.S. healthcare delivery system, providing vital information to help inform public and private decision making.

Providers as Accountable Navigators

Addressing regulations impeding coordinated care: Deputy Secretary Eric Hargan launched a Regulatory Sprint to Coordinated Care, which is examining the burdens created by current regulations under HIPAA, Stark Law, Anti-Kickback Statute, and a substance-use-disorder

information-confidentiality provision called 42 CFR Part 2. The goal is to identify how these regulations may impede care coordination and engage in rulemaking to empower clinicians and other providers to coordinate care and deliver value for patients.

Historic overhaul of physician paperwork requirements: CMS finalized major changes to the requirements in the Medicare Physician Fee Schedule for 2020 regarding "evaluation and management" visits, the first overhaul of this system in decades. The changes moved from five billing categories to three, and radically simplified requirements in order to remove excessive paperwork tied to outdated billing practices.

Paying for Outcomes

Expanding alternative payment models and outcomes-based payment: The share of Medicare beneficiaries covered by alternative payment models—i.e., not based on the traditional fee-for-service system—increased from 13 percent in 2017 to 17 percent in 2018.

Advancing innovative payment models: CMMI saved the federal government and beneficiaries significant amounts of money while maintaining quality through its models:

- The Next Generation Accountable Care Organization model, which allows participants to share in savings through greater care coordination, showed Medicare savings of approximately $100 million in the first-year evaluation.
- The Maryland All-Payer model saved $679 million in total cost of care Medicare savings over the first three years of the model.
- The Repetitive Scheduled Non-Emergent Ambulance Transport model, which aimed to improve use of non-emergency ambulance services in states with high use, reported net savings for the end-state-renal-disease population of $171 million in the first year of the model.

New opportunities for success from ACOs: In 2018, CMS redesigned the Medicare Shared Savings Program for Accountable Care Organizations, or ACOs, which are organizations formed by providers and suppliers that endeavor to improve care and lower costs through coordination. ACOs can be eligible to share in savings generated for Medicare, while eventually being expected to take on risk of sharing losses to the program.

Under the redesigned model, ACOs will have a shorter period to share in savings generated, before having to bear risk for any losses. The redesign of the program aims to improve patients' engagement with their healthcare and give ACOs more opportunities, sooner, to generate savings while bearing risk for costs that exceed benchmarks.

Leveling the playing field for providing healthcare services: In 2018, CMS announced that it would begin paying the same rate for clinic visits whether they are at hospitals' off-campus outpatient departments or at physicians' offices, saving patients $150 million in out-of-pocket costs in 2019 and taking a historic step toward a long-desired goal of "site neutrality" in payment. CMS also finalized changes to allow 17 billing codes for procedures to be paid for by Medicare when they are performed in outpatient settings that may be less expensive and more convenient.

Preventing Disease Before It Occurs or Progresses

Sparking innovation in kidney disease treatment: HHS launched a $2.6 million "Redesign Dialysis" Prize, the first prize competition in the KidneyX initiative, focused on reimagining the current state of dialysis and spurring innovation to create alternative solutions. HHS also signed a memorandum of understanding for the KidneyX public-private partnership with the American Society of Nephrology, solidifying both parties commitment to the prevention, diagnosis, and treatment of chronic kidney disease.

Advancing primary care through Community Health Centers: In 2018, nationally, 67 percent of patients at HRSA-funded community health centers controlled their blood sugar level, an 8 percent increase over the prior year, exceeding the national average of 57 percent. Sixty-three percent of hypertensive health center patients controlled their blood pressure, an increase of 9 percent over the prior year, exceeding the national average of 57 percent.

Tackling diabetes: CMMI's Medicare Diabetes Prevention Program, which was based on the Center for Disease Control and Prevention

(CDC)'s National Diabetes Prevention Program, achieved covered service status under Medicare in 2018, making it the first preventive service model from CMMI to become eligible for expansion and representing a landmark for public health. Twenty-three million American adults with prediabetes are 65 years or older and could directly benefit from this program, and enrollment in CDC's program increased by 128 percent between July 2016 and July 2018.

Addressing social determinants of health to improve independence of older adults and people with disabilities: Older adults and people with disabilities can live in the community, at lower cost and often with better outcomes, if they have access to the right supports. In 2018, the Administration for Community Living (ACL) worked to improve collaboration between healthcare organizations and the aging and disability networks that provide these services and supports. In 2018, at least 74 organizations in ACL's aging and disability networks entered new contracts with integrated care organizations.

Reforming the Individual Insurance Market

One of Secretary Azar's top four priorities is expanding the array of ways Americans can pay for their healthcare, including by reforming and stabilizing the individual insurance market. Under the leadership of Secretary Azar and his senior advisor for health insurance reform, Jim Parker, in 2018 HHS worked with other departments to take significant steps to stabilize the Affordable Care Act exchanges, open up options for patients who cannot find Affordable Care Act (ACA) options that work for them, and expand new healthcare-financing choices that are fiscally sustainable, state-based, and private-sector-driven. Ultimately, empowering patients to finance their care in ways that work for them will support the goals outlined as part of the drive toward a value-based healthcare delivery system.

Historic stabilization of the Affordable Care Act exchanges: After substantial efforts to stabilize the individual market since President Trump took office, average premiums were down and insurer participation was up moving into 2019. In 2018, average benchmark premiums declined by 1.5 percent for plans sold on Healthcare.gov, the first reduction since the Exchange began operating. There are 23 more issuers for 2019 than 2018 and only five states will have one issuer, compared to ten states in 2018. This was the result of actions taken in 2017 and 2018 by the administration to stabilize the Affordable Care Act, including four new reinsurance waivers, all leading to lower premiums, ranging from 9 percent in Maine to 30 percent in Maryland, and resuming the risk adjustment program after a federal judge vacated the methodology from the previous administration.

New affordable options for individual patients: HHS, the Department of Labor (DOL) and the Department of the Treasury finalized a rule to expand the availability of short-term, limited-duration insurance, which can be dramatically more affordable than the plans governed by the ACA—around 50 percent cheaper.

New options for employer insurance: HHS, DOL, and Treasury proposed a rule to allow employers to fund individual market premiums through Health Reimbursement Accounts, which can provide individuals broader access to tax-preferred employer funding. By one estimate, after final implementation of the proposal, 10 million Americans may have access to new insurance options through these arrangements.

Continued reforms of ACA regulations: Building on the Market Stabilization Rule issued in 2017, CMS finalized the 2019 Payment Notice rule that gives states new tools to stabilize their health insurance markets, including more state flexibility and control over essential health benefits, the medical loss ratio standard, network adequacy, risk adjustment, and rate review. CMS also encouraged issuers to sell plans off the exchange without an extra cost sharing reduction load to keep off-exchange premiums lower.

CMS also released new guidance expanding state flexibility to waive certain Affordable Care Act requirements to deliver real alternatives to the ACA that strengthen markets and improve affordability, and released four waiver concepts to illustrate how states can take advantage of this new flexibility.

Improved the consumer experience: CMS's Center for Consumer Information and Insurance Oversight (CCIIO), which runs the federal Affordable Care Act exchange, took a number of steps to maintain or improve the experience for consumers purchasing ACA plans, including:

- Enhancing direct enrollment to provide a new pathway for consumers to enroll in a plan directly through an approved issuer or web broker without needing to be redirected to visit HealthCare.gov, allowing the private sector to offer more user-friendly and seamless experiences for consumers.
- Maintaining an all-time high 90 percent consumer satisfaction rate at the federal exchange call center through the 2019 Open Enrollment Period.
- Investing in the exchange's IT infrastructure resulting in substantially less down time during 2018 and 2019 Open Enrollment versus previous years.
- Responding to agent and broker feedback, including by implementing 93 percent of recommendations to improve the online experience for the federal exchange.

In total, CMS found efficiencies that reduced CCIIO's annual operating budget from $2 billion to $1.87 billion in Fiscal Year (FY) 2018, a 6.8 percent reduction.

New options for small businesses and the self-employed: HHS, DOL, and Treasury expanded the availability of association health plans, or AHPs, which can offer self-employed Americans and those who work for small employers access to plans similar to what larger employers offer.

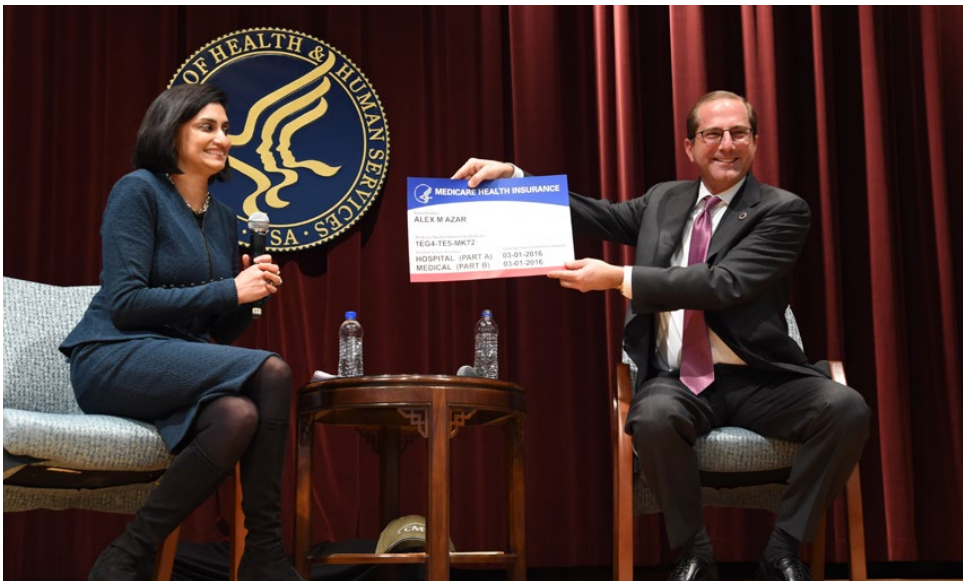
Committing to High-Quality Care in the Indian Health Service

New accessible data on quality: In February 2018, the Indian Health Service (IHS) launched **a new National Accountability Dashboard for Quality** to monitor and report information from across IHS facilities, reporting on key performance data in a succinct and easily viewed display to allow fact-based decisions to ensure quality and safety of care.

A new strategic focus on quality: In December 2018, IHS announced **a new Office of Quality** that will be responsible for providing oversight for quality across the IHS health care system. The office will also support IHS hospitals and health centers by providing a system of quality assurance to attain and maintain compliance with CMS Conditions of Participation and accreditation standards.

A new partnership for quality: IHS began work with the Partnership to Advance Tribal Health (PATH), led by a quality-improvement organization selected by CMS, to identify areas of improvement and best practices across all IHS hospitals and improve quality by implementing best practices and identifying operational improvement needs. The aims of the partnership include improving safety and reducing risk by 50 percent across IHS by creating a harm-free, high-reliability care environment and a learning culture through implementation of a comprehensive patient safety and risk management program by the end of 2022.

Deputy Secretary Eric Hargan participates in a roundtable discussion with patient groups.



CMS Administrator Seema Verma speaks with Secretary Alex Azar.

Modernizing IHS health IT: In September, IHS partnered with the HHS Office of the Chief Technology Officer (CTO) to lead **a Health Information Technology** modernization research project, a one-year effort to assess the current IHS health IT landscape and make recommendations on modernization.

Protecting Patient Privacy

A historic year for HIPAA enforcement: In 2018, the HHS Office for Civil Rights (OCR) had its biggest HIPAA enforcement year in history as its collections, settlements, and judgments totaled over $25.6 million. In October 2018, OCR settled with Anthem, Inc., the largest HIPAA/HITEC Act breach case in history, as measured by size of breach (almost 79 million records, three times the previous record), with the largest recovery in OCR history ($16 million).

Rolling out new Medicare cards: In 2018, CMS mailed out more than 50 million new Medicare cards to seniors, which will help fight fraud and abuse by removing Social Security numbers from their Medicare cards.

Reforms to Increase Accountability and Competition

Expanded competition and choice in Medicare: Changes CMS made to increase competition in both Medicare Advantage and Medicare Part D helped reduce Medicare Advantage premiums by 6 percent for 2019, add more than 600 new Medicare Advantage plan options, increase the number of Part D plans by 15 percent, and lower the average Part D premium for a second year in a row.

Improving payments for home health and skilled nursing facilities: CMS revised its Home Health and Skilled Nursing Payment Systems to reduce the burden imposed by the payment regulations on home-health agencies and nursing-home providers, while offering better incentives for quality services and a greater focus on patients.

Bringing real competition to competitive bidding: CMS overhauled the Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies to address longstanding concerns from some stakeholders that the program was not effectively harnessing market forces.

The first ever Medicaid and CHIP scorecards: CMS began publishing the first simple accountability scorecard regarding basic outcome measures of states' Medicaid and Children's Health Insurance Program (CHIP) programs, providing a new opportunity for understanding and assessing state innovations in healthcare.

GOAL 2

Protect the Health of Americans Where They Live, Learn, Work, and Play

HHS'S WORK TO PROTECT the health of Americans extends from addressing the most pressing public health threats in our local communities, including the opioid crisis, HIV, and other infectious diseases, all the way to supporting global planning and infrastructure to address and prevent health threats around the world.

Combating the Opioid Crisis

In one of his first speeches in office, **Secretary Azar laid out his approach** to the opioid crisis as one of his four priorities, with a specific emphasis on relying on the best science possible. In March 2018, he named Admiral Brett Giroir, Assistant Secretary for Health, as senior advisor to oversee opioid policy and coordinate opioid-specific efforts across the department.

In 2018, under Admiral Giroir's leadership, HHS updated its strategic framework for tackling the opioid crisis, using science as the foundation for the department's comprehensive strategy. These updates built on the five-point strategy to combat the opioid crisis that was developed by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and introduced by HHS under President Trump in 2017.

Dedicated efforts from the federal government to communities and individuals have begun to show promising signs: From 2016 to 2017, according to the HHS-run National Survey on Drug Use and Health, the number of Americans initiating heroin use dropped significantly. From January 2017 through November 2018, there has been a:

- 26 percent decrease in total morphine milligram equivalents dispensed monthly by pharmacies.
- 338 percent increase in naloxone prescriptions.
- 22 percent increase in number of patients receiving buprenorphine, one form of medication-assisted treatment (MAT) for opioid addiction, per month.
- 47 percent increase in number of naltrexone prescriptions, another form of MAT, per month.

Better Access to Treatment, Prevention, and Recovery Services

Historic levels of grant funding: Thanks to legislation passed by Congress and signed by President Trump, HHS awarded more than $2 billion in 2018 to address the opioid crisis. This included:

- The Substance Abuse and Mental Health Services Administration (SAMHSA) awarded $500 million in the second year of the Opioid State Targeted Response (STR) program to help states develop prevention, treatment, and recovery systems to address the opioid crisis. Thanks to STR in 2018, over 121,000 clients received services, 396,000 individuals were trained, and 1,300 funded organizations offered at least one form of MAT.
- SAMHSA awarded $1 billion through the State Opioid Response grant program, building upon the success of STR.
- HRSA awarded more than $350 million to over 1,200 health centers nationwide to implement and advance evidence-based strategies to expand access to integrated substance-abuse and mental health services.
- **The CDC awarded $155 million** to increase support for states and territories working to

prevent opioid-related overdoses, deaths, and other outcomes, which will advance the understanding of the crisis and scale up prevention and response activities. CDC also awarded $12 million in funds to support 11 Tribal Epidemiology Centers and 15 tribal entities, to improve opioid overdose surveillance and improve prevention strategies, and **distributed an additional $27 million** to nine non-governmental organizations, which will support states and territories with staffing, procurement, and training to enhance local public health capacity.

A historic opportunity to test comprehensive interventions: In 2018, the National Institutes of Health (NIH) began accepting applications for the HEALing Communities study, which will provide generous resources and comprehensive support for up to three communities with especially high rates of overdoses, helping them test an integrated set of evidence-based practices for prevention and treatment. HEALing Communities will constitute the most ambitious such undertaking in the history of the study of addiction, while aiming to decrease opioid overdose fatalities in these communities by 40 percent.

A new emphasis on MAT: In one of his first major speeches, Secretary Azar told America's governors that he would make MAT, the gold standard for addiction treatment, a key element of HHS's strategy for battling the opioid epidemic. Toward this end:

- The new SAMHSA SOR grants included a requirement that states make MAT available to all patients served through the grants.
- HRSA-funded community health centers saw a 64 percent increase in MAT patients and 75 percent increase in MAT providers from 2016 to 2017.
- The **Office of the Assistant Secretary for Health (OASH) alerted** healthcare providers to how they can be expanding access to MAT through telemedicine.
- FDA issued two draft guidances on developing buprenorphine depot products, an extended-release form of MAT, and on endpoints for demonstrating effectiveness of MAT drugs.
- SAMHSA developed the first survey of practitioners who are waived to prescribe buprenorphine to better understand barriers to prescribing and the extent to which these constraints can be addressed.
- In 2018, SAMHSA's Medication Assisted Treatment—Prescription Drug and Opioid Addiction program achieved a 62 percent abstinence rate at 6 month follow-up, exceeding its target rate.

Demonstrations to help states use Medicaid to fight addiction: CMS approved 14 substance-use-disorder (SUD) demonstrations in 2018, bringing the total of such demonstrations approved to 21. These demonstrations provide states with new flexibility around the IMD exclusion (Medicaid's statutory restriction on

Secretary Azar and Assistant Secretary for Health Brett Giroir participate take a tour of "Prescribed to Death" — an exhibit aimed at changing Americans' attitudes toward opioids.

funding inpatient treatment for mental illness) to support effective and timely access to treatment for SUD, including opioid use disorder.

A new assessment of such a demonstration, launched by Virginia in 2016, found a number of positive results: The state saw a 39 percent decrease in opioid-related emergency-room visits, and a 31 percent decrease in substance-use-related ER visits overall. The number of residential treatment centers expanded dramatically, as did the number of opioid-specific treatment programs.

Two new payment models: CMMI launched two new innovative models to focus on vulnerable populations—children and pregnant women—in fighting the opioid crisis.

- The Integrated Care for Kids (InCK) model helps prevent and treat behavioral and mental health conditions, including substance-use disorder, in children and young adults. Under the InCK model, when mental and behavioral health challenges arise, there is a full set of crisis services available to handle the needs of kids and their families.
- The Maternal Opioid Misuse (MOM) model allows state Medicaid agencies, front-line providers, and healthcare systems to coordinate clinical care and integrate support services for pregnant and postpartum women with opioid use disorder and their infants.

Supporting rural communities and coalitions: HRSA awarded 95 planning grants to rural communities to identify key needs for prevention and treatment of substance abuse; funded 36 grants to rural communities to combat the opioid epidemic through direct service provision; and awarded $34.6 million to expand the opioid workforce and increase access to evidence-based prevention and treatment services in rural and underserved communities nationally.

Surgeon General's spotlight on the opioid crisis: Surgeon General Jerome Adams's spotlight on the opioid crisis calls for a cultural shift in the way Americans talk about the opioid crisis and recommends actions that can prevent and treat opioid misuse and promote recovery. The Surgeon General also released a digital postcard, highlighting tangible actions that all Americans can take to raise awareness, prevent opioid misuse and reduce overdose deaths.

THE FDA APPROVED THE FIRST NON-OPIOID TREATMENT FOR THE MITIGATION OF WITHDRAWAL SYMPTOMS ASSOCIATED WITH ABRUPT DISCONTINUATION OF OPIOIDS

FDA approvals: The FDA approved the first non-opioid treatment for the mitigation of withdrawal symptoms associated with abrupt discontinuation of opioids; the first generic versions of Suboxone sublingual film; new dosage strength of buprenorphine and naloxone sublingual film as maintenance treatment for opioid dependence; and the first sublingual formulation of sufentanil.

FDA pathways for new treatments: The agency launched an innovation challenge to spur the development of medical devices, including diagnostic tests and digital health technologies (mobile medical applications) to help combat the opioid crisis and achieve the goal of preventing and treating opioid use disorder. FDA received **more than 250 applications** from medical device developers and 8 participants were selected based on the criteria.

New, localized and evidence-based approaches to technical assistance: SAMHSA reconfigured its approach to technical assistance and training, with a new focus on addiction, mental health and substance abuse prevention and making training and technical assistance available to all providers and communities, rather than the former focus just on SAMHSA grantees. SAMHSA also began a first-ever collaboration with the Department of Agriculture, awarding an $8 million effort to develop training and technical assistance centers to address the needs of rural America.

To promote broader use of practices with solid scientific evidence, SAMHSA also established a new National Mental Health and Substance Use Policy Laboratory, which enhances SAMHSA's ability to develop and implement evidence-based resources. SAMHSA introduced its new Evidence-Based Resource Center, replacing an old system which provided little usable information on the establishment of evidence-based practices.

Indian Health Service Principal Deputy Director Michael Weakhee participates in a discussion during the National Town Hall on Combating Opioids and Substance Abuse in Tribal Communities.

FDA work to reduce illicit marketing and distribution of opioids: As part of implementing FDA's Opioid Policy Work Plan, the agency issued warning letters to the marketers and distributors of 12 fraudulent opioid cessation products and to 17 online networks, operating about 370 websites that were illegally marketing unapproved opioids. In June, FDA held the first Online Opioid Summit to discuss ways to reduce the availability of illicit opioids online. In attendance were many key internet stakeholders, including Twitter, Facebook, Microsoft and Google, as well as government agencies, academic researchers and patient advocates.

FDA expands criminal enforcement against illicit opioids: FDA's Office of Criminal Investigations (OCI) established a new Enforcement Task force in partnership with Customs and Border Protection and U.S. Postal Service, while hiring new FDA special agents to step up enforcement. In 2018, OCI made 91 arrests that led to 73 convictions related to the inspections at ports of entry, and increased the use of the TruScan device, a rapid identification tool, to identify counterfeit pharmaceuticals and tainted supplements.

Better Data on the Epidemic

Improving data analysis and dissemination through AHRQ: AHRQ released a new **online statistical resource** in March that, for the first time, provides county-level comparisons of hospitalization rates for substance use, including opioids, alcohol, stimulants, and other drugs. This resource helps communities better understand local challenges and support community efforts to formulate the most effective remedies to reduce substance abuse, including opioid use disorder. AHRQ also published a number of statistical briefs that shine a light on the opioid crisis and its effect on the U.S. healthcare system. AHRQ also expanded its **online resource guide** on integrating behavioral health and primary care to include a section devoted to addressing opioid and substance abuse in primary care In addition to highlighting resources from across HHS, the site includes a collection of over 250 **practical tools and resources** available to providers, patients, and communities to help implement MAT in primary care settings.

Faster counting of overdose deaths: CDC increased the percentage of mortality records collected electronically from the states within 10 days of death from seven percent in 2014 to an estimated 63 percent in 2018, providing faster data to improve decision-making and target resources. CDC also published its first full year of provisional drug overdose death data nationally, for each jurisdiction and specific drugs or drug classes, on a six-month lag, down from a more than 12-month lag.

Advancing prescription drug monitoring programs: CDC supported states to implement important opioid overdose prevention strategies, such as improvements to Prescription Drug Monitoring Programs (PDMPs). With CDC

help, Illinois, for instance, is now integrating PDMP data with more than 800 sites, has completed nearly 4.4 million PDMP requests, and is connected to 25 other state PDMPs to improve usability and state interoperability.

Working toward interoperability of PDMPs: ONC supported the goal President Trump set forth to build a national network of prescription drug programs, through including standards to support **PDMP integration** in the Interoperability Standards Advisory, a process through which ONC coordinates health IT standards and implementation specifications that stakeholders use.

Revolutionizing use of HHS data: Following the HHS Opioid Code-a-Thon in December 2017, HHS released publicly current state assessments about the challenges to data sharing across agencies within the department, including an overview of the relevant legal and privacy landscape—the first of its kind. Born from a winning solution at the HHS Opioid Code-a-Thon, Google will incorporate drug disposal site data into Google Maps, making it easier to find disposal options for unused prescription drugs.

Better Targeting of Overdose Reversing Drugs

Surgeon General's Advisory on Naloxone: The Surgeon General released the first Surgeon General's advisory in 12 years, urging more Americans to carry a lifesaving medication that can reverse the effects of an opioid overdose. Naloxone is already carried by many first responders, such as EMTs and police officers, but the advisory recommends that more individuals, including family, friends and those who are personally at risk for an opioid overdose, also keep the drug on hand. Industry-provided data indicated that there was a 27 percent increase in the number of retail-dispensed prescriptions for naloxone immediately following the release of the advisory and a 70 percent increase in weekly dispensing rates 12 weeks after the release of the advisory.

New HHS naloxone guidance to enhance co-prescribing: **Assistant Secretary for Health Brett Giroir issued a guidance** recommending that clinicians prescribe or co-prescribe naloxone to individuals at risk for opioid overdose, including individuals who are on relatively high doses of opioids, take other medications which enhance opioid complications, or have other underlying health conditions.

Equipping first responders: SAMHSA grants to expand access to naloxone for first responders resulted in the distribution of more than 31,000 naloxone kits during 2018.

Better Pain Management

FDA efforts to improve prescribing and pain management: The FDA awarded a contract to the National Academies of Sciences, Engineering, and Medicine to help advance the development of evidence-based guidelines for appropriate

Secretary Azar visits with a client of Brigid's Path, an inpatient medical care center for drug-exposed newborns.

opioid analgesic prescribing for acute pain resulting from specific conditions or procedures.

The agency also approved the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS), which for the first time applies to immediate-release opioid analgesics intended for use in an outpatient setting. Previously, the REMS had covered only extended-release/long-acting opioid analgesics. Also for the first time, the opioid REMS will require that training be made available to health care providers who are involved in the management of patients with pain, and not only to prescribers.

Overseeing prescribing in Medicare: The HHS Office of the Inspector General (OIG) published **a new report** analyzing Medicare Part D data to identify opioid prescribing patterns. While risky prescribing was down from 2016 to 2017, OIG found that about 15,000 beneficiaries appeared to be "doctor shopping" and that almost 300 prescribers engaged in questionable opioid prescribing by ordering opioids for beneficiaries at serious risk of opioid misuse or overdose.

Better Research on Pain and Addiction

Helping to end addiction long term: In 2018, NIH launched the Helping to End Addiction Long-term (HEAL) Initiative, to accelerate scientific solutions to address the opioid crisis, with regard to both pain and addiction.

With regards to pain, HEAL builds on extensive, well-established NIH research to:

- Develop new tools and biomarkers to detect changes in the brain associated with the transition from acute to chronic pain.
- Develop tailored interventions to control pain and restore function.
- Develop new, effective, and non-addictive approaches for pain management.
- Define and support best practices for pain management.

On addiction, HEAL will also seek to:

- Develop flexible and complementary treatment options for opioid use disorder to reduce drug use, prevent overdoses and support recovery.
- Develop new agents to prevent and reverse opioid overdose that are capable of reversing overdose from highly potent synthetic opioids such as fentanyl and carfentanil.
- Enhance treatments for pregnant women with an opioid use disorder and for newborns with neonatal opioid abstinence syndrome (NAS).
- Develop and test additional medication-assisted treatment options.
- Test strategies for translating research into practice, and advance implementation of evidence-based treatments in real-world settings.

HHS HELD THE DEPARTMENT'S FIRST-EVER NATIONAL CONVENING ON NAS, WHICH BROUGHT NATIONAL EXPERTS TOGETHER TO PROVIDE THEIR INDIVIDUAL PERSPECTIVES ON A NEW HHS INITIATIVE TO STUDY AND ADDRESS THE NEEDS OF INFANTS BORN WITH NAS.

A new initiative on NAS: HHS held the department's first-ever national convening on NAS, which brought national experts together to provide their individual perspectives on a new HHS initiative to study and address the needs of infants born with NAS.

HHS-supported research advances: In 2018, NIH-supported studies that pertain to pain and opioid addiction included the following:

- Researchers demonstrated in the *Journal of Pain* that disability is as likely in the chronic pain population as it is in those with kidney failure, emphysema or stroke—reflecting the challenges faced by 11 million U.S. adults with High Impact Chronic Pain (HICP), a new concept that describes those with pain lasting three months or longer and accompanied by at least one major activity restriction.
- A study published in *Science*, funded in part by the National Institute on Aging, found that clinicians were more likely to reduce the number and dose of opioid drugs they prescribed after learning that one of their patients had died from an overdose from a controlled substance than those not notified.

NIH Director Francis Collins and Secretary Alex Azar participate in a Twitter chat on Pain Awareness Month.

- An NIH-funded study found that treatment of opioid use disorder with either methadone or buprenorphine following a nonfatal opioid overdose is associated with significant reductions in opioid-related mortality.
- Researchers have shown that pain-induced changes in the rat brain's opioid receptor system may explain the limited effectiveness of opioid therapy in chronic pain and may play a role in the depression that often accompanies it, showing the clear impact of chronic pain on the brain and its relation to depression.
- New research published in *Neuron*, funded by the National Institute on Drug Abuse, found that opioids used to treat pain, such as morphine and oxycodone, produce their effects by binding to receptors inside neurons, contrary to conventional wisdom that they acted only on the same surface receptors as endogenous opioids, which are produced naturally in the brain.

Understanding opioid use among Americans with disabilities: ACL's National Institute on Disability, Independent Living and Rehabilitation Research (NIDILRR) launched two projects in 2018 to better understand opioid use and abuse among Americans with disabilities: One will lay the groundwork for primary care providers and specialists to accurately assess for opioid use disorder in people with disabilities who are taking opioids long term to manage musculoskeletal pain, and the other will contribute to evidence-based policy and practice on behalf of people living with disabilities and opioid use disorder.

Promoting and improving best practices: In December, the Pain Management Best Practices Inter-Agency Task Force, hosted by OASH, issued its draft report, calling for individualized, patient-centered pain management to improve the lives of millions of individuals who experience acute and chronic pain. The report will be finalized in 2019.

Strengthening Global Health Security

Launching a new global strategic plan: At the 2018 U.N. General Assembly, a U.S. delegation, led by Secretary Azar and supported by HHS's Office of Global Affairs successfully negotiated a resolution on the International Health Regulations (IHR), resulting in the approval of the IHR Global Strategic Plan, a key piece of strengthening global health security around the globe.

Taking the next steps for global health security: At the 5th Global Health Security Agenda Ministerial Meeting in Indonesia, with HHS Deputy Secretary Hargan as head of delegation, HHS led an international working group to further President Trump and Secretary Azar's priorities for the Global Health Security Agenda (GHSA),

a multinational coalition for global health security. This work resulted in the development and successful international launch of the next five-year phase of GHSA, known as "GHSA 2024," and its guiding framework.

Addressing regional health crises and security: Secretary Azar convened an Americas ministerial roundtable discussion to discuss needs and solutions to the regional health crisis stemming from the collapse of the Venezuelan healthcare system and the mass migration out of the country, which has demonstrated the need for regional partners to cooperate on global health security.

Health security at the southern border: HHS worked to realign the activities of the U.S.-Mexico Border Health Commission according to the administration's infectious disease global health priorities by redirecting FY 2018 and 2019 funding to projects on the border, which advance administration objectives on both global health security and antimicrobial resistance.

Battling America's HIV Epidemic

CDC expands surveillance work: In 2018, the CDC implemented a new integrated HIV surveillance and prevention program to prevent new HIV infections and achieve viral suppression among persons with HIV, enabling health departments to better match resources to geographic burden of HIV. This program builds on CDC's flagship HIV program, a chief contributor to HIV prevention success in the U.S., including increases in awareness of status, and reductions in perinatal HIV infections and new HIV diagnoses.

A new record for results from the Ryan White program: In 2018, 85.9 percent of patients receiving medical care through HRSA's Ryan White Program were virally suppressed, compared with a viral suppression rate of 59.8 percent among the general population of people diagnosed with HIV. Higher rates of viral suppression mean not just better health for those living with HIV, but also substantially reduced likelihood of their transmitting HIV.

New focuses for the Ryan White program: HRSA revamped the Ryan White HIV/AIDS Program (RWHAP) Part C funding methodology to better align with where the epidemic is most concentrated. The new methodology allowed HRSA to fund ten new RWHAP Part C geographic service areas, including six in the South, where there is the greatest burden of infection, illness, and deaths from HIV.

A promising sign about viral suppression: HIV was suppressed for more than 15 weeks through antibody infusions, after stopping antiretroviral treatment, in a pilot clinical trial of a small group of people living with HIV who were sensitive to two anti-HIV antibodies. The trial was supported by NIH, the Gates Foundation, and others.

National Disaster Medical System teams in training.

U.S. Public Health Commissioned Corps officers present the colors at the *2017 Hurricane Response: Joint Services Awards Ceremony* last November.

Fighting Infectious Diseases At Home and Abroad

Promoting innovation in the fight against Lyme disease: The HHS CTO organized and led the first-ever Lyme Innovation Roundtable at HHS to harness the power of collaboration, data-driven Innovation, and emerging technologies for Lyme and other tick-borne diseases. The HHS CTO announced and led the 14-week tech sprint to create value from federal open data related to health priorities like artificial intelligence for improving experimental therapies, matching clinical trials, and responding to Lyme disease. The sprint uses methods pioneered by the Census Bureau for lightweight public-private collaborations that tackle complex challenges with open data, emerging technology, and agile methods.

Taking the lead on fighting to end tuberculosis: HHS led the U.S. Government's participation in the U.N. High-Level Meetings on Tuberculosis (TB) at the U.N. General Assembly, at which the U.S. stance on multi-stakeholder approaches to these challenges as well as a strong commitment to protection of innovation were achieved in the high-level meetings' accompanying declarations. Together, OGA, CDC, NIH, and FDA are working to develop a whole-of-HHS initiative to accelerate TB elimination in the United States and around the world.

Combating Anti-Microbial Resistance

Securing global cooperation against the AMR threat: Recognizing that confronting antimicrobial resistance (AMR) requires cooperation from across nations and sectors, HHS launched the AMR Challenge at the 2018 United Nations General Assembly in September, as an opportunity for governments, corporations, and non-governmental organizations to make pledges to further the progress against AMR.

A new FDA strategy for AMR: In September, Commissioner Scott Gottlieb announced FDA's strategic approach to antimicrobial resistance, launching a new website highlighting the work happening across FDA's programs and issuing a Request for Information to solicit input from the public and private sectors on developing an annual list of regulatory science initiatives specific for antimicrobial products.

Improving stewardship of antibiotics in veterinary settings: A 2018 report from FDA's Center for Veterinary Medicine found that U.S. sales and distribution of antimicrobials approved for use in food-producing animals dropped by 33 percent from 2016 to 2017, suggesting progress in efforts to reduce unnecessary use and improve stewardship. The Center for Veterinary Medicine also published an action plan "Supporting Antimicrobial Stewardship in

Veterinary Settings," which details its goals in this area for Fiscal Years 2019-2023.

Expanding scientific knowledge of AMR: NIH's National Institute for Allergy and Infectious Diseases (NIAID) began supporting U.S. clinical sites participating in two ongoing international Phase 2 clinical trials evaluating investigational antibody-based therapies aimed at preventing potentially antibiotic-resistant infections.

Responding to Natural Disasters

Responding to hurricanes, wildfires, and more: In 2018, the Assistant Secretary for Preparedness and Response (ASPR) led the federal government's public health and medical response to 22 disaster responses, drills, and national special security events including a hurricane season with two of the largest storms ever recorded in U.S. history, as well as the worst wildfire season on record in California. More than 700 HHS personnel deployed for the hurricanes and wildfires and provided care to more than 7,800 patients in impacted areas where hospitals had been destroyed or overwhelmed or evacuated residents needed medical care in shelters. The Assistant Secretary for Health, who leads the U.S. Public Health Service Commisioned Corps, deployed more than 1,050 Commissioned Corps officers to respond to nearly 30 disaster responses, planned events, and community health and services mission.

Over the past year, HHS staff, led by ASPR, dedicated more than 119,000 hours to assist in the recovery of health and social services in communities impacted by the unprecedented 2017 hurricane season. Commissioned Corps officers responded to Hurricanes Florence and Michael, the Hawaii volcano eruption, the California wildfires, Typhoon Yutu, and the NIAID Ebola vaccine trial in Liberia. Through the end of 2018, HHS personnel continued work with recovery efforts from the effects of the 2017 hurricane season in Puerto Rico.

Historic recognition of HHS role in disaster response: For the first time ever, in 2018, Commissioned Corps officers received the Humanitarian Services Medal in recognition of a large-scale deployment, alongside personnel from the Department of Defense, for their work on response and recovery efforts in the wake of the devastation caused in 2017 by Hurricanes Harvey, Irma, and Maria.

Improving systemic preparedness: Building on the success of coalitions among state and local healthcare providers through the Hospital Preparedness Program, ASPR began implementing a vision for a Regional Disaster Health Response System, which draws public and private health care facilities and services together to provide comprehensive care during disasters. Demonstration projects in Massachusetts and Nebraska began in the fall of 2018, taking the idea from concept to design to demonstration in less than a year. In 2018, existing coalitions successfully responded to hurricanes, train derailments, and more. ASPR also led the largest

More than 230 U.S. Public Health Commissioned Corps officers deployed in North Carolina to help residents in the aftermath of Hurricane Florence, including providing care to patients at a shelter in Clayton, NC.

patient movement exercise in the department's history, working with 50 partners from state and local agencies and the private sector to test the nation's readiness for Ebola and other highly infectious disease outbreaks.

Defending against Chemical, Biological, and Radiological Threats

HHS leads the first-ever biodefense strategy: President Trump unveiled the first National Biodefense Strategy and tapped HHS to lead implementation of that strategy to make America safer from all biological threats to national security. The naming of HHS as the lead agency for the National Biodefense Strategy is a culmination of the department's long emergence as a key player on national security, stretching from Secretary Donna Shalala's declaring HHS a national security agency for the first time in the 1990s through the integral role HHS played in responding to the post-9/11 anthrax attacks, new pandemic influenza threats in the 2000s, and the Ebola outbreak of 2014.

A new home for the Strategic National Stockpile: HHS completed the transfer of the Strategic National Stockpile from CDC to ASPR, a reorganization of over $600 million in federal resources, including personnel, records, and assets that provide life-saving pharmaceuticals and medical supplies during a disaster or other public health emergency. The program transfer is expected to increase efficiencies within the HHS medical countermeasure enterprise, appropriately integrating the stockpile into HHS's disaster-response arm.

Work continues toward a universal influenza vaccine: Influenza vaccines need regular updates and vary in effectiveness against seasonal viruses. NIH supports a comprehensive research portfolio to develop more effective vaccines and adjuvants, including "universal" influenza vaccines capable of generating protection against multiple seasonal and pandemic influenza strains. In 2018, the National Institute of Allergy and Infectious Diseases (NIAID) published a Strategic Plan for a Universal Influenza Vaccine was developed focusing on natural history and pathogenesis of influenza infections; influenza immunity and correlates of protection; and the rational design of universal influenza vaccines.

New countermeasures approved: ASPR's Biomedical Advanced Research and Development Authority (BARDA) continued to partner with private industry to develop medicines, vaccines, and diagnostics, nine of which received FDA approval in the past year, bringing the total number of FDA approvals for BARDA-sponsored medical countermeasures to 42. Approvals in 2018 included:

- The world's first approved treatment for smallpox
- A new radiation injury treatment
- Blood screening tests for Zika virus
- Novel spray skin cells for severe burn injuries
- Three new drugs to fight antibiotic-resistant infections

Providing Epidemiological Assistance Here and Abroad

Battling seasonal flu: CDC provided critical response to the 2017-2018 severe flu season, including working with industry to facilitate smoother antiviral distribution, providing timely interim estimates of influenza vaccine effectiveness, and using sequence-first surveillance to improve detection of emerging viruses and candidate vaccine virus selection for the 2018-19 season.

Responding to outbreaks at home: Epidemic Intelligence Service officers and other CDC subject matter experts conducted 50 Epi-Aids to assist state, local, territorial health departments and other public authorities to rapidly respond to infectious or non-communicable disease outbreaks, unexplained illnesses, or natural or man-made disasters. Outbreaks investigated this year included Colorado tick fever, Legionnaires' disease, group A Streptococcus infection, opioid related infections, and youth suicide. CDC also supported responses to multistate outbreaks of hepatitis A with staff deployments, technical assistance, and vaccine procurements, with the resulting evidence base leading the Advisory Committee on Immunization Practices to recommend hepatitis A vaccine for homeless populations.

Responding to outbreaks abroad: CDC provided epidemiology and laboratory support to Uganda during an outbreak of deadly Marburg virus, a viral hemorrhagic fever similar to Ebola, helping limit the number of infected people to only five cases. CDC and partners also

Secretary Alex Azar delivers remarks alongside Surgeon General Jerome Adams and FDA Commissioner Scott Gottlieb during a press event for the Surgeon General's advisory on e-cigarette use among youth.

decreased the number of polio cases worldwide to 24 in FY 2018, a dramatic reduction from 30 years ago, when there were 350,000 cases recorded worldwide.

Responding to Ebola in Central Africa: Two separate Ebola outbreaks in the Democratic Republic of the Congo required global assistance in 2018, and CDC and NIH experts deployed for both responses to support the Congolese government and international partners. Tens of thousands of people have received an investigational Ebola vaccine under compassionate use and millions of border screenings were completed as part of response activities. In November 2018, FDA **issued an emergency use authorization** for the first Ebola fingerstick test with a battery-operated portable reader, allowing use by healthcare providers in the field. Also in November, an international consortium led by the World Health Organization, the Congolese National Institute of Biomedical Research and NIAID launched a randomized **clinical trial** of investigational Ebola therapeutics.

Combating Nicotine Addiction

FDA's comprehensive plan for tobacco and nicotine regulation: The agency successfully advanced a comprehensive plan for tobacco and nicotine regulation by publishing three Advance Notices of Proposed Rulemaking on nicotine, flavors, and premium cigars. FDA also launched its new "Every Try Counts" smoking cessation campaign in 25 markets.

Law enforcement actions on e-cigarette sales: FDA took numerous actions as part of its Youth Tobacco Prevention Plan to help stop youth use of, and access to, e-cigarettes. For example, in the largest coordinated enforcement effort in the FDA's history, **the agency announced in September** it had issued more than 1,300 warning letters and fines to retailers who illegally sold e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores. The agency issued warning letters to companies misleading kids with e-liquids that resemble children's food products, as well as a warning letter to HelloCig Electronic Technology Co. Ltd. for various violations of the Federal Food, Drug, and Cosmetic Act, including selling two e-liquids that contained prescription drugs leading FDA to determine that the products were unapproved new drugs.

Promoting Health through Physical Activity

A new mission for the President's Council: President Trump renamed the President's Council on Fitness, Sports and Nutrition to the President's Council on Sports, Fitness and Nutrition, and charged the HHS Secretary, through the President's Council, to develop a national strategy to expand participation in youth sports, encourage regular physical activity—including active play—and promote good nutrition for all Americans.

Establishing the Council: On May 4, President Trump announced his intent to nominate new members to the Council, including co-chairs Olympic volleyball champion Misty May-Treanor, Super Bowl champion Herschel Walker, and World Series champion Mariano Rivera. On September 21, Secretary Azar kicked off the inaugural annual meeting, where the new members of the President's Council convened to discuss their recommendations for the youth sports strategy and how to address barriers and opportunities to get more kids in the game, particularly those in economically distressed areas, girls, and children with a disability.

New guidelines for physical activity: OASH's Office of Disease Prevention and Health Promotion published the second-ever edition of Physical Activity Guidelines for Americans, in collaboration with CDC, NIH, and the President's Council. The "Move Your Way" campaign launched to promote new Guidelines helped generate 2.5 billion media impressions, with favorable reception to key changes in this edition such as the message that "all activity counts" and the recommendation that Americans should "move more and sit less" throughout the day.

Modernizing Food Safety and Nutrition

Supporting food innovation: As companies prepare to introduce foods derived from cultured animal cells into the U.S. market, providing additional choices for consumers and opportunities for industry, FDA took significant steps toward a regulatory framework for these foods. A deliberative process between FDA and the Department of Agriculture resulted in a combined statement to publicly announce that both agencies intend to jointly oversee the production of cell-cultured food products derived from livestock and poultry.

Empowering Americans with more useful nutritional information: Recognizing that more accessible information about healthy foods could have a significant impact on Americans' health, FDA launched its Nutrition Innovation Strategy and took several meaningful steps to empower consumers with nutrition information, completing draft and final guidance documents to help industry implement the new requirements for updating the Nutrition Facts label and new menu-labeling requirements.

Continuing successful implementation of the FDA Food Safety Modernization Act (FSMA): FDA published more than 20 draft and final guidances related to the FSMA rules, used new tools to help ensure that foods imported into the United States are produced in accordance with the same safety standards required of food produced domestically, and issued new draft guidance regarding the serious situations where the FDA intends to make public the retail locations that may have sold or distributed a recalled human or animal food.

Surgeon General Jerome Adams poses with the "Youth of the Month" during White House Sports and Fitness Day — a day to encourage kids to participate in sports and live an active lifestyle.

Enhancing outbreak response: CDC's PulseNet program has begun using whole-genome sequencing for the most common bacterial foodborne pathogens, which in 2018 resulted in more than 43,000 bacterial strains sequenced and solved at least 18 major foodborne disease investigations, such as the Spring romaine lettuce, packaged vegetable trays, and breakfast cereal outbreaks.

Advancing Drug Safety

Addressing drug shortages: FDA launched the Drug Shortage Task Force, including members from the FDA, CMS, ASPR, the Department of Defense, the Department of Veterans Affairs and the Federal Trade Commission, and began to solicit feedback on the root causes of and enduring solutions to drug shortages.

Supporting safe access to compounded drugs: In an effort to balance safety with the need some patients have for accessing compounded drugs rather than the FDA-approved version of some drugs, FDA issued warning letters and took enforcement actions regarding manufacturers who were not meeting standards for compounding drugs. At the same time, FDA issued new draft guidance regarding the quality of compounded drugs made in outsourcing facilities and traditional pharmacies, to help support safe compounding practices.

Improving Mental Health Treatment

Historic guidance around the IMD exclusion: CMS released guidance on a new demonstration opportunity for states to improve access to mental health services for adults with serious mental illness (SMI) and children with serious emotional disturbance. These services can include community-based services and crisis stabilization services, as well as short-term stays in psychiatric hospitals and residential treatment settings that are ordinarily excluded from Medicaid reimbursement due to the decades-old IMD exclusion. CMS's guidance encouraged states to use these waivers as part of a continuum of care that includes increased integration of mental health services with other health care services, earlier identification of individuals with mental illness, and improved transitions between levels of care.

Expanding the options available for treating SMI: In 2018, FDA approved a batch of first generics for treatment of depressive episodes associated with bipolar depression and for the treatment of schizophrenia, and reclassified **certain uses of electroconvulsive therapy devices**, for treating catatonia or a severe major depressive episode associated with major depressive disorder or bipolar disorder, from a class III to a class II medical device, involving slightly less strict controls for this narrow but effective therapeutic application of such devices.

IN 2018, AN NIH-SUPPORTED CLINICAL TRIAL DEMONSTRATED THAT DIALECTICAL BEHAVIOR THERAPY, EFFECTIVE IN REDUCING SUICIDE-RELATED BEHAVIOR IN ADULTS, CAN ALSO REDUCE ADOLESCENT SUICIDE ATTEMPTS AND SUICIDAL BEHAVIOR.

Building on progress of the ISMICC: After the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC) was established in 2017, under the 21st Century Cures Act, SAMHSA met the congressional requirement to develop, in conjunction with other federal departments, a comprehensive report to Congress including recommendations to address SMI. Acting on these recommendations, SAMHSA has formed five specific workgroups around: 1) strengthening federal coordination, 2) establishing evidence-based treatments, 3) addressing populations involved in the justice system, 4) closing the gap between what works and what is offered, and 5) developing financing strategies to increase affordability and accessibility.

Supporting research on treatments for SMI: Findings from the large-scale Recovery After an Initial Schizophrenia Episode (RAISE) project demonstrated that a team-based interdisciplinary treatment program outperformed usual treatment for first episode psychosis.

Understanding SMI interventions: ASPE-led projects analyzed the effectiveness of coordinated specialty care for psychosis, mental health parity, Community Behavioral Health Clinics, and

Secretary Alex Azar is joined by Secretary of Education Betsy DeVos, Assistant Secretary for Mental Health and Substance Use, Dr. McCance-Katz, and Wisconsin First Lady Tonette Walker during a Federal Commission on School Safety field visit at Adams-Friendship Middle School in Adams County, Wisconsin.

assisted outpatient treatment, all policy interventions under consideration by the ISMICC.

Studying suicide prevention: Suicide prevention also continues to be a priority area for NIH.

In 2018, an NIH-supported clinical trial demonstrated that dialectical behavior therapy, effective in reducing suicide-related behavior in adults, can also reduce adolescent suicide attempts and suicidal behavior. NIH intramural researchers developed and made available a free resource—the Ask Suicide-Screening Questions toolkit—in multiple languages to help clinicians identify youth at risk for suicide. NIH also collaborated with the Mental Health Innovation Network and other federal partners on the Reducing the Incidence of Suicide in Indigenous Groups–Strengths United through Networks (RISING SUN) toolkit to help clinicians, communities, policymakers, and researchers measure the impact and effectiveness of suicide prevention efforts in rural and tribal communities.

Advancing school safety and mental health treatment: Secretary Azar represented HHS alongside the Secretaries of Education, Homeland Security, and Justice on the Federal Commission on School Safety, which was established in March 2018 by President Trump and sent its final report to the President in December 2018. HHS's investigation included participation by Secretary Azar and Assistant Secretary McCance-Katz in listening sessions and site visits nationwide. HHS's contributions to the report covered the integration of behavioral health services into schools, the use of psychotropic medications for children, and ways that federal privacy laws such as HIPAA and FERPA apply to mental health issues and treatment in schools. In part as a result of HHS work on the commission, in July, SAMHSA established technical assistance and training to support school-based mental health services at each of its twelve Mental Health Technology Transfer Centers (one is located in each HHS region, one serves American Indian and Alaska Native communities, and one serves Hispanic American communities).

GOAL 3

Strengthen the Economic and Social Well-Being of Americans Across the Lifespan

FROM DELIVERING HEALTH VISITS for new moms and supporting Early Start locations across America, to the development of aging and disability networks to help older Americans live in their communities longer than ever before, HHS plays a vital role in providing human services to vulnerable Americans at all stages of life.

This work is often done in cooperation with state and local governments, as well as community and faith-based organizations, allowing services to be delivered in a locally driven, person-centered manner. In 2018, these efforts involved a special emphasis on the value of work and community engagement to physical and mental well-being, as well as prioritizing respect for life from conception until natural death. Finally, in 2018, HHS recognized the 40th anniversary of NIDILRR, which played a pioneering role in many of the tools and practices that Americans with disabilities use today to live independently, and the Independent Living Programs, which provide tools, resources and supports for fully integrating people with disabilities into their communities.

Boosting Health, Work, and Upward Mobility

Promoting physical and emotional well-being through community engagement: In 2018, CMS approved the first-ever state demonstrations to incentivize work and community engagement among certain adult Medicaid beneficiaries. By year's end, demonstration authority had been granted to five states, and CMS had also issued guidance to assist other states in applying for demonstrations.

Incentivizing work within child support: The Office of Child Support Enforcement and Office of Family Assistance within the Administration for Children and Families (ACF) issued an information memorandum to promote the use of IV-D incentive funds and cash-welfare funds to promote employment programs for noncustodial parents.

Aiming for independence: The ReImagine HHS Aim for Independence initiative worked with states to develop a vision for an ACF Center of Excellence to drive program integration and outcomes and empower families to sustain economic independence. ASPE provided original analysis to the Aim for Independence effort regarding marginal tax rates, program integration, human services policy, qualitative and economic analysis, and work promotion.

Promoting fatherhood in human services programs: ACF issued **guidance** to all states emphasizing the importance of meaningful father engagement in all ACF programs to better serve children and families. The agency also released a **report** showing healthy marriage and responsible fatherhood programs administered by ACF have positive impacts.

Addressing unacceptable employment gaps for Americans with disabilities: In 2018, ACL established a multi-agency task force for increasing employment opportunities for people with disabilities, which includes the 11 federal agencies that have a role in this issue. This represents an unprecedented level of coordination and commitment to addressing the huge gaps in employment between Americans with and without disabilities. (In 2017, according to the Bureau of Labor Statistics, 8 out of 10 people with disabilities were unemployed as compared to 3 out of 10 people without disabilities.)

Deputy Secretary Eric Hargan visits an Indian Health Service-supported clinic in Allakaket, Alaska, to discuss healthcare delivery in frontier settings.

Supporting Independence of Older Adults and People with Disabilities

Expanding opportunities for veterans to maintain independence: In 2018, ACL and the Department of Veterans Affairs (VA) significantly expanded the Veteran-Directed Care program, which helps veterans who are eligible for nursing home care live in their communities. Specifically the program allows veterans to use a flexible service budget to design and direct their care and services based on their unique needs—as defined by them, including hiring family, friends and neighbors to provide the services they need. Veterans in the program are supported by counselors provided by the aging and disability networks funded by ACL.

In 2018, five additional VA Medical Centers began partnering with 27 organizations in ACL's aging and disability networks. Studies have shown that three veterans can be served through the program for the same cost as serving one veteran in a nursing home. With 2018's expansion, a total of 67 VA Medical Centers are working with 232 aging and disability network agencies to offer the program in 39 states.

Advancing Tribal Programs and the Government-to-Government Relationship

Recognition of new tribes: In April, IHS leadership and the HHS Office of Intergovernmental and External Affairs met with six newly federally recognized tribes in Richmond, Virginia. This followed President Trump's signing the "Thomasina E. Jordan Indian Tribes of Virginia Federal Recognition Act of 2017," which provided federal recognition to the Chickahominy Indian Tribe, Chickahominy Tribe Eastern Division, Rappahannock Tribe, Monacan Nation, Nansemond Indian Tribe, and Upper Mattaponi Tribe.

Building the government-to-government relationship: HHS's Office of Intergovernmental and External Affairs hosted eleven Regional Tribal Consultations across the country, as well as one Annual Budget Consultation in Washington, D.C. In addition, three Secretary's Tribal Advisory Committee meetings were hosted, including one in Alaska with the Deputy Secretary visiting Alaska Native villages, which was the largest and most comprehensive series of tribal meetings and site visits in HHS history.

New pilot for supporting recovery from substance abuse in tribal communities: In February 2018, the IHS Division of Behavioral Health **awarded $1.62 million** for the Youth Residential Treatment Center Aftercare Pilot Project

program, to the Healing Lodge of the Seven Nations in Spokane Valley, WA, and Desert Sage Youth Wellness Center in Hemet, CA. The pilot aims to develop innovative and collaborative strategies to improve the health of American Indian and Alaska Native youth as they transition from residential care back into the communities in which they live.

Making progress against diabetes in Indian Country: In June 2018, a report on 10-year outcomes of participants in IHS's Special Diabetes Program for Indians was published in *Diabetes Care*, a monthly journal of the American Diabetes Association, confirming the long-term effects of moderate weight loss achieved through an intensive lifestyle intervention such as the Special Diabetes Program in reducing the risk of type 2 diabetes among American Indian and Alaska Natives.

Protecting Life and Conscience Rights

A new strategic commitment to life: In February 2018, HHS updated its five-year Strategic Plan for 2018-2022, which highlights that a core component of HHS's mission is the dedication to protecting the life of all Americans at every stage of life, beginning at conception.

New Title X proposed regulation to protect life: In June 2018, HHS proposed a new Title X regulation that would enforce statutory program integrity provisions by no longer permitting Title X-funded family planning services at the same location where abortion is provided. In its most recent Title X grant awards, HHS funded 12 organizations that were not current Title X grantees, including state health departments, a faith-based organization, and several community health centers.

New Civil Rights division to protect conscience and religious freedom: In January 2018, OCR launched a new Conscience and Religious Freedom Division, the first time a federal office for civil rights has established a separate division dedicated to ensuring compliance with and enforcement of laws that protect conscience and free exercise of religion in healthcare and human services.

Protecting conscience in health insurance: In November 2018, HHS, DOL, and Treasury issued two final rules to provide regulatory relief to American employers, including organizations like the Little Sisters of the Poor, which have religious or moral objections to providing coverage for contraceptives, including those they view as abortifacient, in their health insurance plans. The departments are vigorously defending the final rules.

New proposed conscience regulation: HHS proposed a rule in January 2018 to strengthen enforcement procedures for 25 health-related federal conscience and religious freedom laws and enforce those laws as vigorously as other civil rights laws enforced by OCR.

Lynn A. Johnson, Assistant Secretary, Administrator for Children and Families, welcomes Secretary Alex Azar on ACF Adoption Day.

HHS leaders at the announcement of the new Conscience and Religious Freedom Division launched by HHS's Office for Civil Rights.

New protections from paying for abortion in the Affordable Care Act: In November 2018, HHS issued a proposed rule to require issuers of ACA exchange plans to bill and send separate invoices for insurance coverage for non-Hyde abortions. In April 2018, CMS issued guidance to allow individuals to claim a hardship exemption from the ACA's individual mandate if all affordable plans offered through the federal exchanges in an individual's area included abortion coverage, contrary to the individual's beliefs.

Rescinded guidance that limited states' ability to take action against abortion providers: In January 2018, CMS rescinded an April 2016 guidance that curtailed states' ability to set reasonable standards for determining which providers can participate in their Medicaid programs.

Protecting life abroad: HHS worked with the Department of State to implement President Trump's restored and expanded Mexico City Policy, known as "Protecting Life in Global Health Assistance," to ensure that, consistent with applicable law, global health assistance administered by HHS is not provided to foreign non-governmental organizations that provide or promote abortion as a method of family planning. At international forums—such as the United Nations, the World Health Organization, and the Pan American Health Organization—HHS continued to fight the concept of abortion as a fundamental human right, as evidenced by statements, votes called, amendments offered, and resolutions opposed.

Strengthening Faith-Based Cooperation

Expanding faith-based efforts on HIV/AIDS: OGA led and planned, in collaboration with the State Department, a PEPFAR Faith Community Technical Summit, convening faith-based organization and community leaders to discuss and coordinate activities to reach epidemic control, through specific focus on men and children and stigma reduction.

Working with faith-based partners on addiction: HHS's Center for Faith and Opportunity Initiatives connected nearly 14,000 faith and community leaders and providers with information, resources, and practical strategies for addressing the opioid crisis in their communities. The center also hosted a national convening with over 60 faith-based recovery support providers, to help them play a role in the expansion of evidence-based practices for addiction, including MAT.

GOAL 4

Foster Sound, Sustained Advances in the Sciences

HHS IS PROUD to be home not just to many of the world's preeminent individual scientists, public health experts, and clinicians, but also the world's finest scientific institutions: the largest single source of biomedical research funding in the world in NIH, the world's premier epidemiological institution in CDC, and the world's gold-standard food and drug safety agency in FDA.

In 2018, work continued to maximize the impact these institutions have on improving the health and well-being of Americans and the entire world, while various efforts were undertaken to improve the underlying infrastructure of our research, approval, and public health work.

Accelerating Biomedical Innovation

Speeding innovation for military medical needs: In 2018, FDA established a **framework for enhanced collaboration** with the Department of Defense (DoD) to expedite the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. In support of this partnership, FDA:

- Granted an **Emergency Use Authorization** for a freeze-dried plasma requested by DoD, and **issued a draft guidance** on the development of dried plasma products intended for transfusion.
- Approved, six months ahead of DoD's product development schedule, an auto-injector device as a medical countermeasure for chemical nerve agent exposure.
- Partnered with DoD on **regulatory science research** to help speed potential countermeasures for Ebola and other viruses.
- **Signed an MOU** with DoD setting forth the framework for the ongoing partnership and the creation of a robust program that can better serve the health care needs of American military personnel.

FDA and WHO working together to expedite review of HIV treatments: FDA announced a plan to work with the World Health Organization (WHO) to pilot a process to share documents on HIV drug applications that have been approved or tentatively approved by the agency under the U.S. President's Emergency Plan for AIDS Relief. In this initial pilot, the FDA will, with the applicants' permission, provide the WHO with minimally-redacted reviews of one or two HIV drug applications, which can then be used to produce review dossiers to be shared with regulators in resource limited countries to speed up their own regulatory review processes.

Working toward international regulatory harmonization: FDA expanded the United States' ability to use drug inspections conducted by competent European authorities by completing capability assessments for 15 European Union (EU) regulatory authorities, which are now recognized as capable authorities under the Mutual Recognition Agreement between the FDA and EU that went into effect in November 2017. FDA also promoted future access to safe, effective and affordable generic drugs by securing the International Council on Harmonization's endorsement of FDA's proposal for future harmonization of scientific and technical standards for generic drugs.

Paving the way for a digital-health future: FDA made significant strides toward implementing its Digital Health Innovation Plan, which is focused on fostering innovation at the intersection of medicine and digital health technology.

For instance, FDA issued three significant draft guidances to implement the 21st Century Cures Act, including clarifying the regulatory status of products that contain some functions fall outside the scope of FDA regulation, but others that do not.

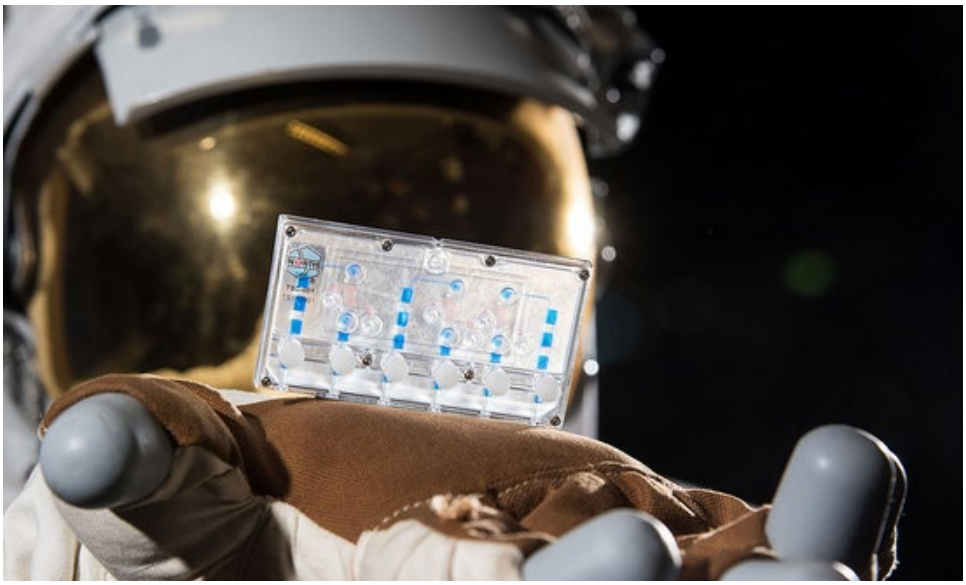
Advancing science in outer space: On HHS's behalf, Deputy Secretary Hargan signed an **interagency agreement with NASA**, covering cooperation on scientific research that would benefit humanity on Earth and on individuals traveling to the Moon and beyond. NASA and various HHS agencies have mutual interests in exploring autonomous portable medical capabilities for remote locations and field medical care, long shelf life and manufacturing of pharmaceuticals, and improved tools to deal with isolation and confinement. The National Institutes of Health already had its own agreement with NASA, but this new interagency agreement is an umbrella arrangement designed to cover the entire Department of Health and Human Services.

Harnessing Real World Evidence

Building real-world evidence through partnerships: In collaboration with FDA, the National Evaluation System for health Technology (NEST) Coordinating Center established agreements with twelve data partners representing over 195 hospitals, nearly 4,000 clinics and over 495 million patient records. Soon, NEST will launch pilot programs testing the use of medical records, patient registries and claims data to evaluate the safety and effectiveness of devices in many clinical areas and throughout the medical device total product life cycle. Both FDA and CMS serve on the NEST Governing Committee, as improved data collection through NEST can also help establish the evidence needed for CMS national coverage determinations.

Using real-world evidence in regulatory decisions: FDA developed guidance for the use of electronic health records and claims data as Real World Evidence to support regulatory decision making and held multiple public meetings and workshops to discuss how regulatory decision making can adapt to permit the use of complex innovative designs—such as simulations or trials without placebos—in clinical trials of drugs and biological products.

Launching the All of Us research program: In May 2018, NIH launched the All of Us Research Program, an effort to engage 1 million U.S. research volunteers to build a national resource that accelerates health research and individualized healthcare. To date, over 150,000 individuals initiated sign up to join the program, with over 64,000 of these individuals already contributing data as participants. The size of the program will enable researchers to derive insights especially for populations that are traditionally underrepresented in biomedical research.



A NASA spacesuit is shown with a kidney tissue chip in hand, part of a partnership between the NIH's National Center for Advancing Translational Sciences (NCATS) and the ISS National Lab.

Photo: NASA

Expanding the evidence base to increase organ donation: HRSA established a pilot registry for living organ donors tracking the long-term outcomes of living donations to allow HRSA and NIH an opportunity to study the long-term implications of living donations.

Making Strides in the War on Cancer

NIH and VA collaborate to boost veterans' access to cancer clinical trials: Veterans with cancer who receive treatment from the VA will now have easier access to clinical trials of novel cancer treatments, thanks to an agreement between VA and the National Cancer Institute (NCI). The NCI and VA Interagency Group to Accelerate Trials Enrollment, or NAVIGATE, which is launching at 12 VA facilities across the country, will enhance the ability of veterans to participate in trials carried out through NCI's National Clinical Trials Network (NCTN) and the NCI Community Oncology Research Program.

Advancing the Beau Biden Cancer Moonshot: The $300 million appropriated for the Beau Biden Cancer Moonshot in FY 2018 has been invested in research focused on speeding progress against cancer in children and adults though advances in immunotherapy and the understanding of drug resistance. The moonshot efforts were enhanced by the FY 2018 launch of NIH's Partnership for Accelerating Cancer Therapies, a five-year public-private collaboration between NIH and 12 biopharmaceutical companies to develop biomarkers to advance cancer immunotherapy.

A major initiative on drivers of cancer in black men: NIH and the Prostate Cancer Foundation launched a large study on aggressive prostate cancer in black men, the largest coordinated research effort to study biological and non-biological factors associated with this issue. The $26.5 million study, called RESPOND, or Research on Prostate Cancer in Men of African Ancestry: Defining the Roles of Genetics, Tumor Markers, and Social Stress, will investigate environmental and genetic factors related to the aggressiveness of prostate cancer in African-American men to better understand why they disproportionally experience aggressive forms of the disease compared with men of other racial and ethnic groups.

New discoveries expanding our understanding of cancer: Scientific discoveries in 2018 around cancer that were supported by NIH funding include:

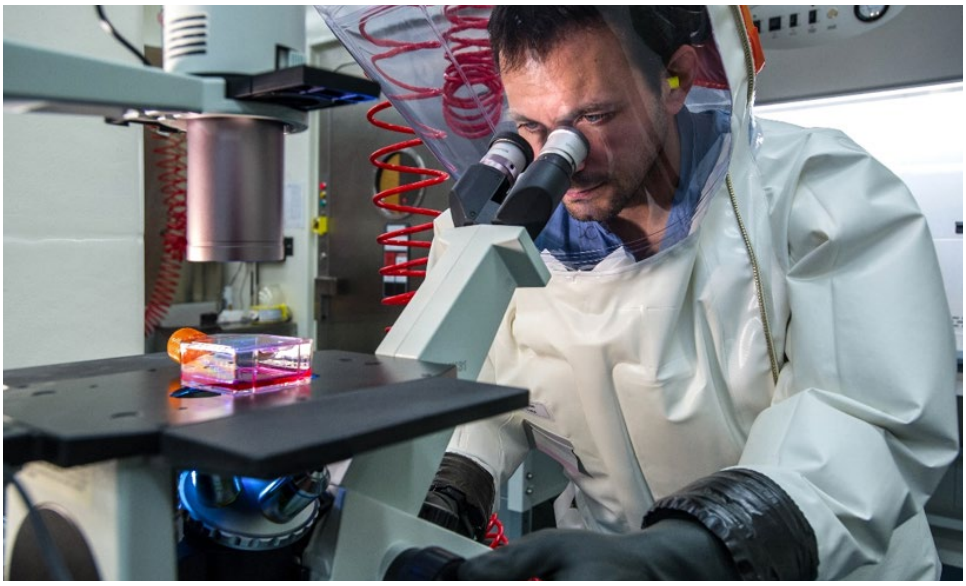
IN MAY 2018, NIH LAUNCHED THE ALL OF US RESEARCH PROGRAM, AN EFFORT TO ENGAGE 1 MILLION U.S. RESEARCH VOLUNTEERS TO BUILD A NATIONAL RESOURCE THAT ACCELERATES HEALTH RESEARCH AND INDIVIDUALIZED HEALTHCARE.

- A combination of two drugs was found in an interim analysis of a Phase 3 clinical trial to be superior to the standard treatment for some patients with chronic leukemia.
- A novel approach to immunotherapy developed by researchers at NCI has led to the complete regression of breast cancer in a patient who was unresponsive to all other treatments.
- Findings from the groundbreaking Trial Assigning Individualized Options for Treatment ("TAILORx trial") showed no benefit from chemotherapy, as opposed to hormone therapy alone, for 70 percent of women with the most common type of breast cancer.
- Interim results from a randomized clinical trial for patients with patients with certain rare sarcomas show that a drug extended progression-free survival compared with a placebo.

Prioritizing Other Breakthrough Research Areas at NIH

The next steps in regenerative medicine: In 2018, FDA continued to make strides in advancing the field of regenerative medicine. The field of regenerative medicine may allow engineered cells and tissues to grow healthy, functional organs to replace diseased ones; allow genes to be introduced into the body to combat disease; and allow adult stem cells to generate replacements for cells that are lost to injury or disease.

To support the growth of this field, FDA issued numerous draft and final guidance documents



Scientists from the Centers for Disease Control and Prevention investigate, monitor, and control sickness, disability, and death caused by highly lethal viral, bacterial, prion, and related infections and diseases of unknown origin.

addressing topics such as risk-based compliance and enforcement priorities regarding the premarket approval requirements for human cell and tissue-based products, as well as expedited programs for regenerative medicine therapies for serious conditions. At NIH, therapeutic strategies supported by $10 million FY 2018 funding include cell delivery for restoring the structure and function of damaged cells and tissues and enhancing the body's own innate healing capacity.

Revolutionizing our understanding of the human brain: NIH moved forward with its inter-agency BRAIN Initiative, which seeks to develop technologies that will revolutionize understanding of the human brain in health and disease, in part by developing a dynamic map of individual cells and complex neural circuits to understand how they interact and what happens in brain diseases.

Specific goals for NIH contributions to the initiative were formulated in "BRAIN 2025: A Scientific Vision," a 12-year roadmap. NIH used the $86 million in FY 2018 that was authorized by the 21st Century Cures Act to support, among other initiatives, the BRAIN Initiative Cell Census Network, to catalog brain cell types across species, and an interdisciplinary and integrative BRAIN Circuit Programs to link neural circuit activity to behavior. Continuing to build on early research successes, NIH also announced more than 200 new BRAIN awards totaling over $220 million.

Researching sickle cell disease: NIH's National Heart, Lung, and Blood Institute launched the Cure Sickle Cell Initiative, a collaborative effort to accelerate the development of genetic therapies to cure the disease, which affects 100,000 Americans, disproportionately impacting African-Americans.

Researching the progression of Parkinson's: As part of the Accelerating Medicines Partnership (AMP), NIH and partners launched AMP Parkinson's Disease, to focus on identifying and validating promising markers of the disease to track progression and eventually develop biological targets for discovery of new drugs.

Seeking a better understanding of Down Syndrome: NIH launched the INCLUDE (Investigation of Co-Occurring Conditions Across the Lifespan to Understand Down Syndrome) project, dedicating $22.2 million in additional funding to raise NIH's total Down Syndrome research funding to approximately $59 million for FY 2018.

GOAL 5

Promote Effective and Efficient Management and Stewardship

IN 2018, HHS took major steps forward in departmental management, from reforms of the regulatory burdens it places on healthcare and human services partners to developing new tools for improving departmental management. As the single largest cabinet agency by spending, representing more than one-third of the total federal budget, HHS also maintained its reputation for excellence in budgetary management and enhanced its financial practices. HHS was ranked as the second best large federal agency — and the best cabinet department — to work at for the second straight year.

Stopping Healthcare Fraud

Records set by OIG: HHS's Office of the Inspector General participated in the largest national Healthcare Fraud Takedown Day in history, charging over 600 individuals with participating in fraud schemes involving about $2 billion in losses to Medicare and Medicaid. Since the last takedown, OIG also issued exclusion notices to 587 doctors, nurses, and other providers based on conduct related to opioid diversion and abuse. In the 2018 takedown, 162 defendants, including 76 doctors, were charged for their roles in prescribing and distributing opioids and other dangerous drugs.

As one example of a particularly large fraud, an owner of a Florida pharmacy was sentenced to 15 years in prison and ordered to pay $54.5 million for a prescription drug fraud scheme. The owner operated multiple pharmacies, which he used to pay kickbacks and bribes in exchange for prescriptions and submitted false claims for prescription compounded medications to private insurance companies, Medicare, and Tricare.

New significant reductions in Medicare improper payments: CMS lowered the rate of improper payments in Medicare fee-for-service to 8.12 percent (almost a 10 percent decrease from last year's rate), a $4.59 billion decrease from 2017 to 2018 and the lowest rate since 2010. Corrective actions in skilled nursing facility payments resulted in $1.04 billion decrease in estimated improper payments from 2017 to 2018, while corrective actions in the durable medical equipment program resulted in a $1.14 billion decrease in estimated improper payments from 2016 to 2018.

Regulatory Reform and Simplification

Leading on regulatory reform: In Fiscal Year 2018, HHS reduced the present-value economic burden of its regulations by $12.5 billion. This included 25 deregulatory actions, compared with just 4 regulatory actions—a 5:1 ratio, far outstripping the overall administration goal of a 2:1 ratio.

HHS was the No. 1 Cabinet agency in terms of deregulatory impact for Fiscal Year 2018. This work was coordinated across the department by the Deputy Secretary's office and HHS's Regulatory Reform Task Force, and aligned with the Office of Management and Budget's Unified Agenda by HHS's Executive Secretariat.

Improving processes and flexibility for state healthcare programs: From 2016 through the first quarter of 2018, CMS cut the median approval time for a state plan amendment by 23 percent, while approval times for waivers for long-term care- and home-and-community-based-services dropped as well. CMS also issued a proposed rule that will help streamline

regulation of states' use of managed care for Medicaid and CHIP, and published a letter to state Medicaid directors explaining its current approach to calculating budget neutrality for 1115 demonstrations, to address concerns raised by some states.

Lessening clinician burden: At CMS alone, regulatory reform measures will generate $5.2 billion in savings from 2018 to 2021, saving clinicians more than 53 million hours of paperwork and eliminating 105 different clinical measures because they were unhelpful or no longer meaningful.

Streamlining compliance for health centers: HRSA issued the Health Center Program Compliance Manual, centralizing compliance guidance into a single resource that reduced the number of the pages in the compliance guide by more than 50 percent, resulting in GAO closing a 2012 recommendation.

Moving Forward with ReImagine HHS

A department-wide effort to advance HHS operations launched in 2017, ReImagine HHS saw initiatives formally launched and a number of results begin to materialize in 2018.

Advancing acquisitions through 'Buy Smarter' initiative: Utilizing Blockchain technology, artificial intelligence, and machine learning, the ReImagine HHS acquisitions-reform initiative, "Buy Smarter" developed a secure, immutable automated data layer to provide the HHS workforce with real-time, agency-wide data for effective decision making throughout the acquisition process. Buy Smarter has trained HHS personnel in more agile approaches to acquisitions, improved the interaction with industry partners at both transactional and strategic levels, and significantly lessened the administrative and financial burden on small businesses. Buy Smarter has identified opportunities to achieve over $720 million a year in savings on HHS-wide goods and services once fully implemented. For this work, the initiative won two noteworthy awards at the 2018 Government Innovation Awards, which showcases the best examples of discovery and innovation in government IT.

Improving employee engagement and management: ReImagine HHS's "Maximize Talent" initiative to improve human resource practices helped HHS retain its spot as the No. 2 best large agency to work at in the federal government in 2018. Maximize Talent has been implementing four distinct projects to transform the HHS workplace experience at all stages of the employee lifecycle. 1) A reform of the enterprise-wide hiring processes to increase collaboration across the HHS Human Resources Centers; 2) an employee engagement initiative that established tools and processes for managers to use to routinely measure and implement activities to improve overall employee engagement; 3) an initiative to transform HHS' performance management culture, which included a proposal for a new HHS Performance Management Policy and Performance Plan; and 4) a reform of the HHS-wide human resources IT infrastructure.

IN 2018, HHS RECEIVED, FOR THE FIFTH CONSECUTIVE YEAR, THE PRESTIGIOUS ASSOCIATION OF GOVERNMENT ACCOUNTANTS' "CERTIFICATE OF EXCELLENCE IN ACCOUNTABILITY REPORTING," THE HIGHEST AWARD AVAILABLE FOR FEDERAL GOVERNMENT FINANCIAL REPORTING.

Building Budgetary and Operational Excellence

Recognitions of accounting performance: In 2018, HHS received, for the fifth consecutive year, the prestigious Association of Government Accountants' "Certificate of Excellence in Accountability Reporting," the highest award available for federal government financial reporting. HHS also received an unmodified or "clean" audit opinion, from the independent audit of the department's annual financial statements. In total, ASFR's Office of Finance presented annual spending for over 300 programs in HHS' audited financial statements and maintained highly complex accounting structures and standard business processes to account for over $1.7 trillion in budgetary resources.

Improvements in grants processes: ASFR's Office of Grants and Acquisition Policy and Accountability (OGAPA) continued to improve the experience for applicants and grantors through Grants.gov. The site posted 5,798 funding opportunities and processed over 227,160 applications through the Grants.gov system, running 100 percent operational with no unscheduled outages. In April 2018, OGAPA successfully launched the Grants.gov Mobile App, providing applicants with new notification tools and convenient access to search, view, and share federal funding opportunities on the go. OGAPA also implemented other process enhancements that support more robust reuse of data from previous applications, reduce the burden on applicants during the application process, and allow streamlined account creation and logins.

Specific HHS divisions also endeavored to simplify grants applications, with SAMHSA significantly streamlining its application review process by reducing the application length from 25 to 10 pages and reducing the number of questions to which applicants had to respond from over 25 to 9.

New progress on the Medicare appeals backlog: The Office of Medicare Hearings and Appeals (OMHA) removed more than 224,000 appeals from its appeals backlog in fiscal year 2018, bringing the total number of pending appeals down to 417,198 at the end of the fiscal year. Progress resulted from both traditional hearing and adjudication by administrative law judges as well as special initiatives including innovative solutions such as the use of alternative dispute resolution techniques through OMHA's settlement conference facilitation program. After receiving a 70 percent increase in funding over FY 2017 levels for FY 2018, continued through FY 2019, OMHA also began the staffing and geographic expansions necessary to address its current appeals backlog and position the agency to timely address future appeals.

Digitizing departmental processes: The Departmental Appeals Board launched a project to digitize all remaining paper files in its Medicare Operations Division, which will transform the case processing of Medicare appeals into a completely paperless process.

OMHA achieved a significant milestone in its multi-year Electronic Case Adjudication and Processing Environment initiative, beginning an incremental rollout to a limited number of teams of administrative law judges beginning in early December. In 2018, over 1,000 appeals were also filed through a new pilot electronic portal for appeals, a 216 percent increase from 2017.

Maximizing the Promise of Data

Scorecards for top departmental priorities: ASPE began creating monthly measurements of progress under the Trump administration toward the expansion of MAT and naloxone prescribing, as well as reductions in the volume of opioids prescribed. ASPE also enhanced its data and

Agents from HHS OIG office participated in largest healthcare fraud takedown in June 2018.

modeling capacity to track a broad range of spending trends in brand, generic, biologic, and specialty drug markets, including tracking list-price increases in near real time. With these metrics, the entire department, from leadership on down, can gain the earliest possible sense of where policy changes may be having an effect.

Tracking substance abuse and overdoses: SAMHSA re-instituted the Drug Abuse Warning Network, a critical system that lapsed seven years ago and provides national surveillance hospital data on issues related to drug use and overdose. SAMHSA also focused specifically on addressing its data collection activities. SAMHSA revised the network's data collection instruments to collect diagnosis and program-specific information which was not previously collected. SAMHSA national survey data has also been enhanced to collect enhanced information around recovery, MAT provision, and kratom.

Achieving universal participation in reporting on elder abuse: In 2018, for the first time, all 50 states contributed data to the ACL's voluntary National Adult Maltreatment Reporting System, which collects data on elder abuse and abuse of people with disabilities as reported to adult protective services, and also the volume, response, and, eventually, outcomes of adult protective services work. Lack of data for research and best practice development has been cited by numerous entities, including the Government Accountability Office, as a significant barrier to fighting elder abuse.

Promoting interoperability—in human services: ACF established an interoperability action plan to expand data sharing initiatives within ACF and beyond. ACF's Office of Planning, Research, and Evaluation has convened a community of interest to facilitate implementation of the plan across ACF programs.

HRSA recognized for data stewardship: HRSA developed a Modern Data Analytics Platform (MDAP) to enable more data driven decisions across HRSA by automating data collection and data analysis, and improving data reporting, a project which won the prestigious American Council for Technology and Industry Advisory Council Igniting Innovation Award.

Improving assessments of outcomes for refugees: ACF's Office of Refugee Resettlement (ORR) expanded the data collected from state and state-alternative agencies, focusing on enrollment and outcomes. ORR expanded this data collection as one of the many efforts to enhance data collection to better understand program outcomes, service utilization and the continuum of services post arrival.

Improving Research Infrastructure at NIH

Boosting next-generation researchers: As a result of the NIH Next Generation Researchers' Initiative, in 2018, NIH funded far more early career investigators than at any time in NIH history.

Leveraging the cloud: In 2018, NIH launched the NIH STRIDES—Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability—Initiative to use commercial cloud computing to provide NIH researchers access to the most advanced, cost-effective computational infrastructure, tools, and services available. NIH has partnered with Google Cloud and Amazon Web Services to reduce economic and technological barriers to accessing and computing on large biomedical data sets.

Mapping human biology: NIH launched the Human Biomolecular Atlas Program (HuBMAP) to develop an open, global framework that will support research community efforts to map the adult human body at the level of individual cells. The new round of funding launched in 2018 totals $54 million over the next four years.

Protecting the Security of the United States Biomedical Research Enterprise

Increasing role for HHS in protecting national security: In 2018, through the Office of Security and Strategic Information, HHS played a significantly increased role in cases overseen by the Committee for Foreign Investment in the United States (CFIUS), which reviews the national security implications of foreign investments in U.S. companies. In FY 2018, 14 new CFIUS cases involving HHS were opened, with 11 cases closed, while in FY 2019, four new cases have been opened already and six have been closed.

APPENDIX

HHS by the Numbers

HHS BY THE NUMBERS

Lowering the High Price of Prescription Drugs

OVER 2,000 GENERIC DRUGS

approved or tentatively approved in 2017-18, including 128 in October 2018 — a new FDA record for one month

$17.2 BILLION

in projected savings over five years for American patients and taxpayers from the International Pricing Index (IPI) model

NEW NEGOTIATING TOOLS

provided to Medicare Advantage plans that deliver

15-20% DISCOUNTS

in the private market

$320 MILLION

in savings for seniors in 2018 from changes to Medicare payments for Part B drugs administered in 340B hospital clinics

1st

proposal to include drug prices in direct-to-consumer advertising

$26 BILLION

in estimated savings from generic drugs approved during the Trump administration in 2017 and 2018

57%

fewer brand price increases in 2018, from May 11 to December 31, as there were in 2017, over that same time period[1]

2 BILLS

were signed by President Trump to ban pharmacy gag clauses so patients can always ask for the cheapest option

1. *Source: AnalySource as of January 7, 2019*

HHS BY THE NUMBERS

Reforming Health Insurance Markets

10 MILLION AMERICANS

projected to have access to ***more insurance choices*** *from their employer after full implementation of a proposal to expand Health Reimbursement Accounts*

1.5%

reduction in national average of benchmark premiums on HealthCare.gov, the first-ever drop

40-50%

PREMIUM SAVINGS FOR PATIENTS

making use of expanded short-term, limited duration insurance options that may make more sense for some patients than unsubsidized ACA plans

90%

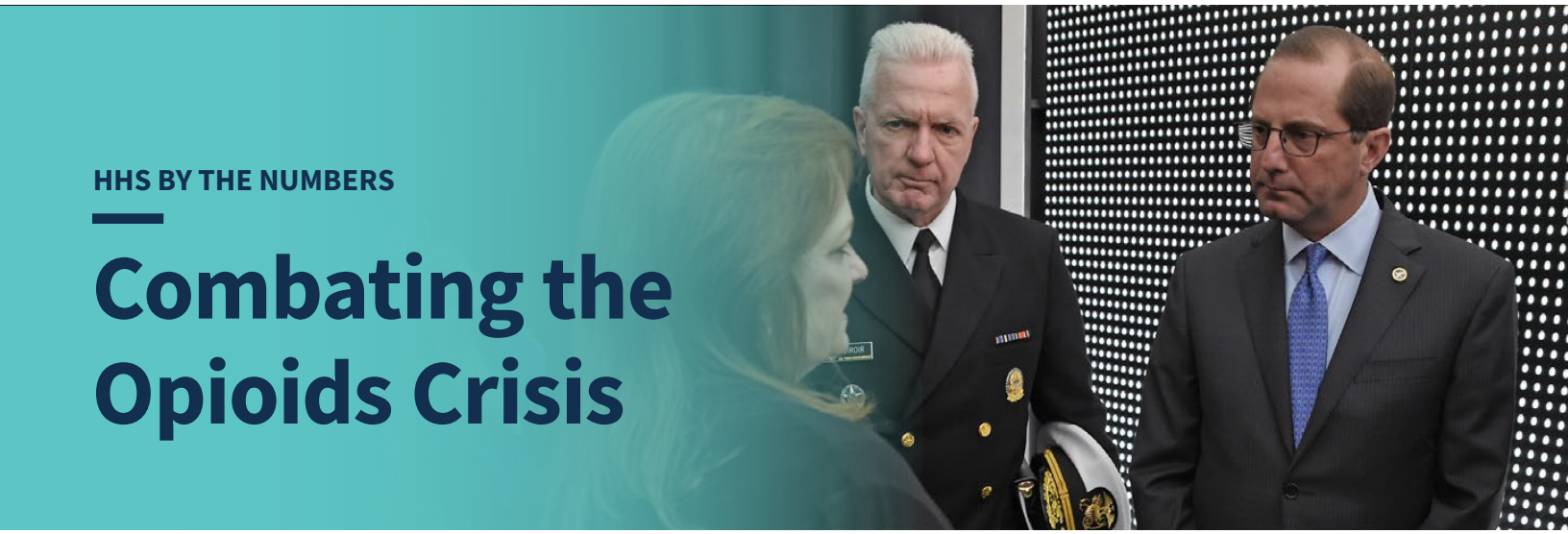
average consumer satisfaction rate through HealthCare.gov call center during open enrollment

23

new individual insurance issuers offering plans on HealthCare.gov

9-30%

reductions in premiums in 4 states granted reinsurance waivers in 2018



HHS BY THE NUMBERS

Combating the Opioids Crisis

367%

increase in naloxone prescriptions per month from January 2017 to October 2018[1]

$2 BILLION+

in grants from HHS to states, tribes, and local communities to fight the opioids crisis in FY 2018

162

defendants charged for prescribing or distributing opioids and other dangerous drugs as part of the largest Healthcare Fraud Takedown Day in history

64% *increase in medication-assisted treatment patients at HRSA-funded community health centers*

state waivers in Medicaid to expand access to inpatient options for substance-use disorder

From Jan. 2017 to Oct. 2018

21% *increase in number of patients receiving buprenorphine monthly*[2]

22% *reduction in opioids dispensed monthly by pharmacies*[3]

9

separate grant program set-asides by SAMHSA for tribal communities, which have been hit especially hard by opioid addiction

14,000

faith and community leaders connected with information, resources, and practical strategies for addressing the opioids crisis in their communities

1st

Surgeon General's Advisory since 2005, urging more Americans to carry naloxone to reverse overdoses

1. IQVIA National Prescription Audit. Data Retrieved on November 14, 2018.
2. IQVIA Total Patient Tracker. Data Retrieved on December 3, 2018.
3. This figure is based on the reduction in total morphine-milligram equivalents (a measure of opioid activity) dispensed.

HHS BY THE NUMBERS

Advancing Value-Based Healthcare

$380 MILLION

in 2019 savings estimated from Medicare paying the same for some services regardless of site of care

$2.26 MILLION

in potential prizes to be awarded by the KidneyX Redesign Dialysis competition to improve care for Americans with kidney disease

The Agency for Healthcare Research and Quality's 2018 National Scorecard on Rates of Hospital-Acquired Conditions (HACs) found HACs fell by **8 PERCENT** from 2014 to 2016, saving approximately **8,000 LIVES**.

First

overhaul of the documentation and coding requirements for physicians' evaluation and management visits in 20 years

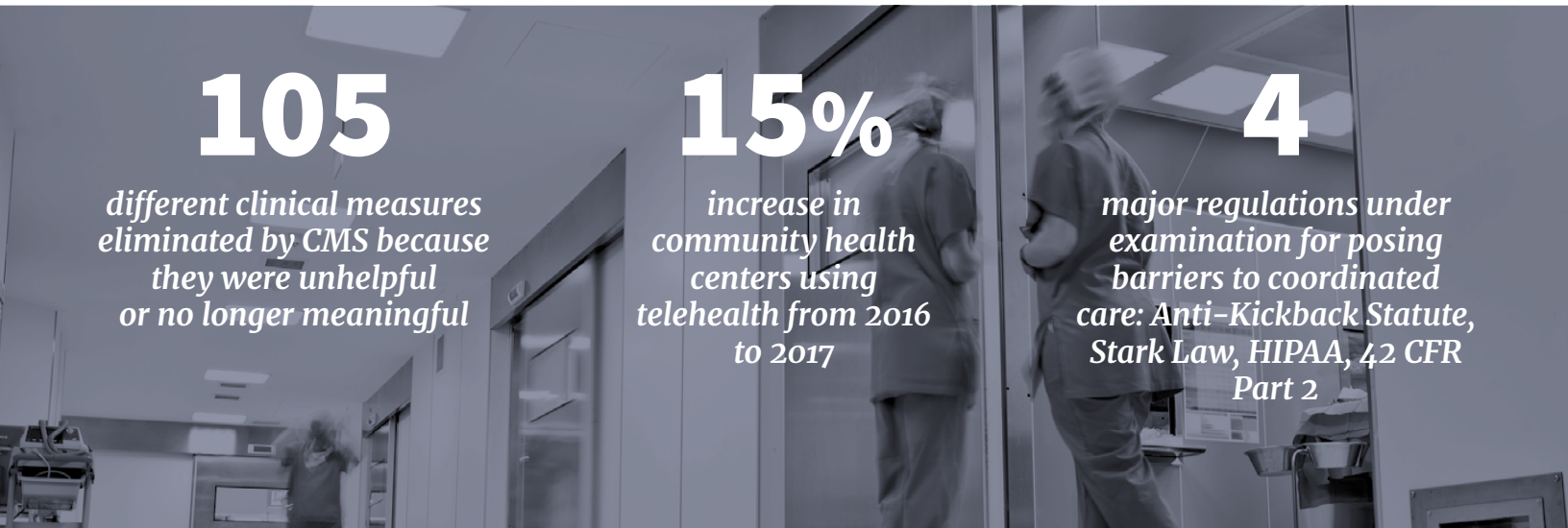
FIVE MODELS PUT FORTH BY CMMI

1. **International Pricing Index**
   5-year projection of $17.2 billion saved
2. **Maryland Total Cost of Care**
   Prior model saved $679 million in 3 years
3. **Maternal Opioid Misuse**
   Targeting the opioid crisis
4. **Integrated Care for Kids**
   Preventing substance abuse such as opioid addiction
5. **BPCI Advanced**
   Innovating with bundled payments

2017 → 2018

13% → 17%

share of Medicare beneficiaries in alternative payment models



105

different clinical measures eliminated by CMS because they were unhelpful or no longer meaningful

15%

increase in community health centers using telehealth from 2016 to 2017

4

major regulations under examination for posing barriers to coordinated care: Anti-Kickback Statute, Stark Law, HIPAA, 42 CFR Part 2

HHS BY THE NUMBERS

Advancing Biomedical Research and Innovation

***Significant reductions** in mortality found in NIH-funded studies of both buprenorphine and methadone as medication-assisted treatment for opioid use disorder*

Combination HIV antibody infusions safely maintained viral suppression for more than **15 WEEKS** in select individuals who stopped antiretroviral therapy in an NIH-funded study

495

million patient records incorporated in new real-world evidence agreements between providers, the National Evaluation System for Health Technology Coordinating Center, and the FDA

200 +

new awards totaling over $220 million as part of the NIH BRAIN (Brain Research Through Advancing Innovative Neurotechnologies) Initiative

Research from CDC's PulseNet program solved at least **18 major foodborne disease investigations** in 2018 and sequenced more than **43,000 bacterial strains**.

100,000

Americans living with sickle cell disease who may benefit from NIH's launch of the Cure Sickle Cell initiative

59

novel drugs or biological products approved by FDA in 2018, a record year

150,000

people across the U.S. have registered to be part of NIH's unprecedented long-term All of Us Research Program

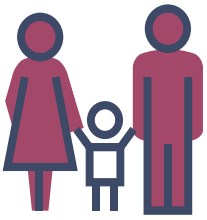
HHS BY THE NUMBERS

Protecting Conscience and Life

HHS Office for Civil Rights establishes

THE FIRST

Conscience and Religious Freedom Division, to protect foundational conscience rights



PROVIDED REGULATORY RELIEF

to American employers, including organizations like the Little Sisters of the Poor, that have religious or moral objections to providing coverage for contraceptives, including those they view as abortifacient, in their health insurance plans

Proposed rules that issuers of Qualified Health Plans (QHPs) *must bill and send separate invoices for insurance coverage for abortions of pregnancies not threatening the life of the mother or resulting from rape or incest, and must offer at least one QHP in each area that doesn't cover those abortions*

The Trump administration does not recognize abortion as a method of family planning and refuses to fund abortion in global health assistance

HHS continues to fight the concept of abortion as a fundamental human right on the international stage

TITLE X PROPOSED REGULATION:

HHS would no longer permit Title X-funded services at the same location where abortion is provided

HHS awarded funding to 12 organizations that were not current Title X grantees

New CMS guidance allows an individual to claim a hardship exemption if all affordable plans on a federal exchange include abortion coverage, contrary to the individual's beliefs

In the process of finalizing rule to strengthen enforcement for 25 health-related federal conscience and religious freedom laws, treating them the same as other civil rights laws

HHS updated its 5-year Strategic Plan highlighting that a core component of HHS's mission is the dedication to protecting the life of all Americans at every stage of life, beginning at conception

HHS BY THE NUMBERS

Excellence in Departmental Management

For the second year in a row, HHS has been ranked the best cabinet department to work at in the federal government

HHS Buy Smarter Initiative receives 2018

BEST IN CLASS

at the Government Innovation Awards

HHS EMPLOYEES WON 3 OF 8

Service to America awards in 2018

224K

Medicare appeals removed from the backlog in Fiscal Year 2108, over one third of the pending backlog

*HHS receives Honorable Mention for **"A by May" initiative** at the 2018 FITARA Awards*

OPERATIONAL EXCELLENCE

at HHS in Management in 2018 in Employee Morale, Information Technology, Grants and Acquisitions, Legal and Regulatory, and Budget

HHS BY THE NUMBERS

Global Health and Health Security

Deployed CDC experts in response to two separate Ebola outbreaks in the Democratic Republic of the Congo, with tens of thousands of people receiving the Ebola vaccine

24

polio cases worldwide, down from 350,000 cases 30 years ago, thanks to work by CDC and partner countries

33%

decline from 2016 to 2017 in prescribing of antimicrobials for livestock, helping address the threat of antimicrobial resistance

9

new medical countermeasures approved by FDA and supported by the Biomedical Advanced Research and Development Authority (BARDA), bringing BARDA's total to 42

Marburg, Ebola, Rift Valley Fever, Plague

just some of the disease outbreaks CDC assisted in combating around the world in 2018

President Trump launched the

FIRST

National Biodefense Strategy, naming HHS as the lead agency for biodefense

HHS BY THE NUMBERS

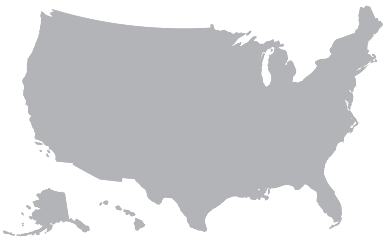
Excellence in Human Services

$18 MILLION

in grants to ten regional partnerships focused on improving outcomes for foster children affected by substance abuse

FIRST

ever Administration for Children and Families (ACF) data interoperability plan launched, to improve data sharing within ACF and beyond



ALL 50 STATES

reported for the first time to the National Adult Maltreatment Reporting System, a database to combat abuse of elders and adults with disabilities

11

federal agencies involved in a new Administration for Community Living (ACL) task force on increasing employment for people with disabilites

5

VA medical centers started Veteran Directed Care programs with ACL's aging and disability networks, allowing veterans to choose services that help them stay in their homes

HHS BY THE NUMBERS

Keeping Americans Safe from Natural Disasters

7,800+

patients cared for by HHS personnel in hurricane- or wildfire-affected areas

1,400+

U.S. Public Health Service Commissioned Corps officers received the Defense Department's Humanitarian Service Medal for hurricane response efforts

FIFTY EPI-AIDS

from CDC to assist state, local, or territorial health departments to rapidly respond to natural or man-made disasters, disease outbreaks, or unexplained illnesses.

1,050+

U.S. Public Health Commissioned Corps officers, and other HHS staff, deployed to respond to two of the largest storms in U.S. history, the worst wildfire season on record in California, other natural disasters, national emergencies, and other public health crises.

$59 MILLION

in one-time grants to assist 162 HRSA-funded community health centers with their disaster response and recovery activites

229

public health and medical responses, drills, and national special security events led by the Assistant Secretary for Preparedness and Response

HHS BY THE NUMBERS

Achieving Regulatory Reform

$12.5 BILLION

in present value of economic burden reduced through HHS regulatory reform in FY 2018

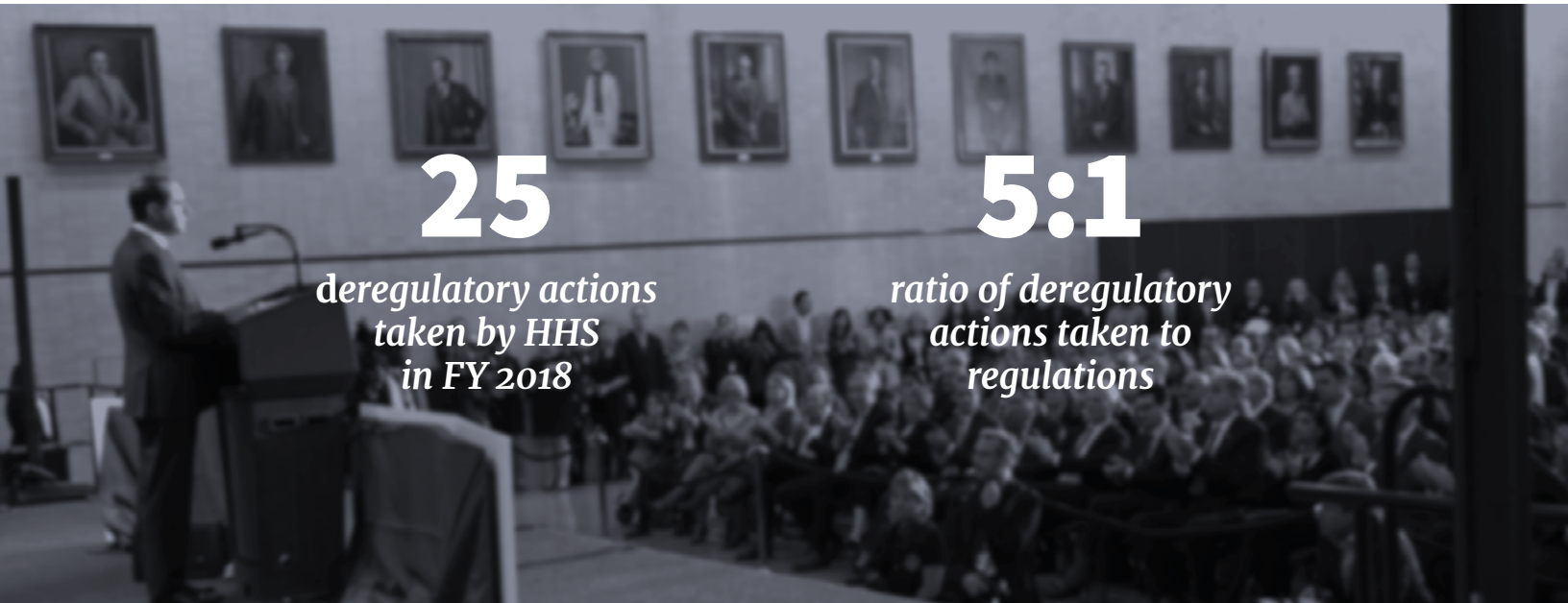
HHS responsible for over half the deregulatory burden reduction for entire Administration in 2018

HHS ranks #1

AMONG ALL CABINET AGENCIES FOR

Deregulatory Savings in FY 2018

Number of Deregulatory Actions



25

deregulatory actions taken by HHS in FY 2018

5:1

ratio of deregulatory actions taken to regulations

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