

## U.S. Department of Health and Human Services

### Answers to National Governors Association Questions on Vaccine Distribution and Planning

**Note:** We appreciate the continued partnership with our Nation's governors on COVID-19 response and recovery efforts. Since the spring, the Federal government has partnered with state, local, and tribal leaders to develop this whole-of-government plan and we will continue this collaboration. We recognize this process is iterative and welcome governors along with other state, local, and tribal officials' input and best practices. The answers provided below were developed by the U.S. Department of Health & Human Services (HHS) in partnership with our Federal partners including the Centers for Disease Control & Prevention (CDC) and the U.S. Department of Defense (DoD), among others.

#### A. Funding for Vaccine Administration

##### **1. Will there be funding allocated to states to assist with distribution of the vaccine and other vaccine efforts?**

To date, CDC has provided \$200 million to states in support of Operation Warp Speed (OWS) efforts on COVID-19 vaccine readiness and \$140 million to states for enhanced flu activities in order to successfully manage the vaccine distribution program.

The next tranche of COVID vaccine readiness funding of \$140 million will be awarded by December 15<sup>th</sup> in order to expand this readiness work and fill initial gaps.

Further planning is underway to make additional resources available to states to support management and operations of vaccine administration and to implement a new delivery infrastructure necessary to deliver the vaccine.

Additionally, OWS has further funding set aside to support distribution and administration, including expanding vaccine safety systems, connecting vaccine information systems, centralized distribution costs and support to state and local communication programs to encourage vaccination.

In considering funding needs, states should recognize that most of the major costs of a vaccine campaign are already being covered. For example:

1. Securing vaccines and most accompanying supplies will cost the state nothing as these are paid for by the federal government;
2. Almost all transportation of a vaccine is covered, either through the manufacturer or through McKesson, the contractor being paid to move the vaccine to administration sites throughout the country;
3. Providers who administer the vaccine will be paid through insurance reimbursement under Medicare and Medicaid, or private coverage;

*This document is iterative and will be updated as new information becomes available.*

4. Healthcare providers who vaccinate uninsured persons will receive reimbursement through the federal uninsured fund managed by Health Resources and Services Administration (HRSA), which has already been covering the cost of care for uninsured COVID-19 patients;
5. Training for most of the healthcare provider workforce to administer the vaccine will be covered in large part by their employing institutions, be it hospitals, pharmacy chains, or other large healthcare entities.

**2. Without additional state and local funding to implement COVID-19 vaccine plans, we will be hampered in what we can accomplish. When can we expect more definitive information about resources related to this response?**

Addressed in Question 1.

**3. What are the plans for any federal contracts and/or additional funding to support “boots on the ground” to vaccinate in tiers 2 and beyond?**

While the federal government generally has not supplied federal support for analogous efforts in testing, actions have been taken (including PREP Act amendments) to ensure that states have access to healthcare workers in their states. Additionally, since existing clinical infrastructure will be heavily relied upon, many workers who can administer vaccines will already be on-site.

**4. How will vaccine administration costs be covered for people who are uninsured?**

Providers who administer the vaccine will be paid through insurance reimbursement under Medicare and Medicaid, or private coverage. Healthcare providers who vaccinate uninsured persons will receive reimbursement through the uninsured fund managed by HRSA, which has already been covering the cost of care for uninsured COVID-19 patients.

- <https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-coverage-life-saving-covid-19-vaccines-therapeutics>

**5. Will the federal government be setting guidelines around allowable vaccine administration costs for those with health insurance (whether that is state insurance, Medicaid, Medicare, Children’s Health Insurance Program (CHIP), or some other state funded health insurance)?**

**How will funding/reimbursement for vaccines be handled?**

Any vaccine doses purchased by the U.S. Government will be provided to Americans at no cost. It is our obligation to ensure every American is provided with a Food and Drug Administration (FDA) approved, safe, effective and affordable vaccine as fast as possible, and vulnerable American who needs the vaccine will receive the vaccine regardless of their ability to pay.

Under Sec. 3713 of the CARES Act, Congress provided coverage under Medicare Part B for the COVID-19 vaccine and its administration without any cost sharing with respect to an FDA-licensed, COVID-19 vaccine. The Centers for Medicare and Medicaid Services (CMS) is exploring coverage options for a COVID-19 vaccine authorized under an Emergency Use Authorization (EUA).

Under President Trump's leadership private insurers, including Humana, Cigna, UnitedHealth Group, and the Blue Cross Blue Shield system committed to waive cost-sharing payments for treatment related to COVID-19 for plan members, and HHS is using a portion of the \$100 billion Provider Relief Fund to reimburse healthcare providers, at Medicare rates, for COVID-related treatment of the uninsured.

**6. We understand that the vaccine will initially be provided at no cost, as was remdesivir. However, states now must pay for remdesivir on the commercial market. How long will the federal government commit to providing the vaccine to states cost-free?**

Vaccines will be provided to the states at no cost with the goal of making enough vaccine available to any person who wants to be vaccinated during the pandemic phases of vaccination.

***B. Allocation and Supply Chain***

**7. How will the vaccine be allocated to states? What formula will be used?**

The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction. The jurisdiction's immunization program will then be responsible for managing and approving orders from enrolled providers within their jurisdiction using this allotment. The amount allotted will change over time, which may be based on critical populations recommended for vaccination by Advisory Committee on Immunization Practices (ACIP) (with input from National Academies of Sciences, Engineering, and Medicine), COVID-19 vaccine production and availability, and overall population of the jurisdiction.

Federal agencies and additional commercial partners will also receive allocations directly from CDC once larger volumes of vaccine are available. CDC is currently developing procedures to ensure that jurisdictions and tribes have full visibility of COVID-19 vaccine supply and vaccination activities among these entities located within their boundaries. Further details are noted on page 24 of the CDC's COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.

**8. How will the vaccine be distributed? What mechanism will the federal government use?**

In most cases, the vaccine will be distributed by McKesson Corporation in partnership with carriers directly to health care provider sites. If the FDA authorizes or approves the Pfizer

vaccine, Pfizer will manage distribution of their vaccine directly to providers. The vaccines and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 providers. Further details are noted on page 25 of the CDC's *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*.

**9. Can the administration provide more guidance on what prioritization requirements will be a condition of vaccine release and to what extent will states have latitude to guide these decisions?**

OWS will direct distribution to jurisdiction-identified locations from the Federal level in accordance with approved allocations during Phase 1. Jurisdiction health officials will then direct local administration.

During the early phases of distribution when vaccine supply may be limited, the CDC will make recommendations on priority populations for vaccination based on recommendations from CDC's independent ACIP. Considerations will include the specific safety and efficacy of the approved vaccine for various demographics. States are not bound to follow federal prioritization recommendations, however we expect that leaders at every level of government will share a commitment to protect populations most vulnerable to COVID-19 and frontline healthcare workers.

**10. Are any further Public Readiness and Emergency Preparedness (PREP) Act changes anticipated beyond authorizations for pharmacists and interns to administer vaccine?**

PREP Act amendments may be authorized in the future, however at this time, most eligible healthcare providers have been allowed to administer any COVID-19 vaccine. A series of recent announcements are below:

- HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic: <https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html>
- Trump Administration Takes Action to Expand Access to COVID-19 Vaccines: <https://www.hhs.gov/about/news/2020/09/09/trump-administration-takes-action-to-expand-access-to-covid-19-vaccines.html>
- Trump Administration Takes Action to Further Expand Access to Vaccines, COVID-19 Tests: <https://www.hhs.gov/about/news/2020/10/21/trump-administration-takes-action-further-expand-access-vaccines-covid-19-tests.html#:~:text=Today%2C%20under%20the%20leadership%20of,technicians%20and%20State-authorized%20pharmacy>

**11. How is CDC planning to manage vaccine distribution to Federal entities such as Federal Prisons, the Department of Veterans Affairs (VA) and other Federal organizations? Will these entities receive a vaccine supply directly from the CDC or will states manage it?**

Several federal partners will be receiving allocations directly from the CDC, and will be responsible for authorized vaccine administration for their respective populations. OWS has incorporated liaison officers from each of these Federal partners to include Bureau of Prisons, the Indian Health Service (IHS) and others in the vaccine operations center at HHS. This ensures close coordination throughout vaccine implementation planning and execution between these agencies, OWS, and the CDC.

**12. Similarly, when can states expect guidance from the federal government on the states' responsibility to vaccinate federal employees (e.g., who is vaccinating National Guard, USPS employees, FBI, etc.)**

The CDC Vaccine Task Force is in regular, ongoing, communication with state health officials providing answers to these types of questions as federal partner vaccination plans are refined. The federal partners responsible for their own vaccinations are the DoD, Department of State, Bureau of Prisons, VA, IHS, and Department of Homeland Security. The majority of the rest of the federal workforce will be vaccinated in accordance with the ACIP's recommended immunization schedule through state-licensed vaccine providers.

**13. How will tribal sovereignty be respected? The CDC sent a template asking how many vaccine doses need to be sent to each IHS/tribal health facility rather than asking states where each tribe wants their vaccine doses sent (which could be one of those facilities, a Department of Health (DOH) public health office, a private provider that they'd like to contract with, etc.)**

Tribal sovereignty is being respected by asking tribal nations how they want vaccine distribution to their people to occur - through the state allocation or through the IHS. States will be informed of any tribes who will depend on states for vaccines.

In terms of tribal decisions on vaccine prioritization within their communities, CDC recommends that tribal nations follow ACIP recommendations. However, the federal government respects tribal sovereignty and their right to provide vaccines in a manner determined by the tribe to be most beneficial.

Tribal populations are considered at increased risk for complications from COVID-19 due to several factors, including limited access to health care, increased likelihood of living in rural areas or in multigenerational housing, and have higher rates of underlying medical conditions.

#### **14. What will be the national strategy for vaccine prioritization when supply is short?**

CDC is using its expertise in public health preparedness and response and its immunization infrastructure to support OWS in planning for vaccine distribution. Our goal is to safely, effectively, and efficiently implement a COVID-19 vaccination program immediately after FDA authorizes or licenses and the ACIP recommends a vaccine and the CDC Director adopts that recommendation. While the end goal is to offer vaccines to the entire U.S. population, identifying priority groups for COVID-19 vaccination is critical for implementation planning.

ACIP formed a COVID-19 Vaccine Work Group in April 2020 to help inform its evidence-based approaches to COVID-19 vaccination policy, including the initial vaccine prioritization strategy to be presented to the full ACIP for deliberation at public ACIP meetings, development of recommendations, and eventual presentation to the CDC for consideration in determining population prioritization. ACIP embarked on early planning in hopes of preventing distribution delays post vaccine approval. ACIP public meeting information can be found at this [link](#).

Given that many decisions regarding the vaccine will depend on the vaccine itself, some specifics concerning distribution will mature as a vaccine (or vaccines) are approved to be safe and effective. Based on current public ACIP discussions, initial populations recommended for COVID-19 vaccination will likely be those in the critical workforce who provide healthcare and maintain essential functions of society, as well as those at highest risk of developing complications from COVID-19, depending on supply.

A committee convened by the National Academy of Medicine (NAM) at the request of the National Institutes of Health and CDC published a *Framework for Equitable Allocation of COVID-19 Vaccine* ([www.nap.edu/read/25917/chapter/1](http://www.nap.edu/read/25917/chapter/1)) on September 30, 2020. These findings have been shared with ACIP and will help inform the committee's deliberations related to vaccine priority groups and ensuring equity in vaccination in the United States. CDC is also leveraging lessons learned from 2009 H1N1 pandemic vaccine implementation to guide COVID-19 vaccine prioritization.

#### **15. How will management of supplies (i.e. needles, syringes, alcohol pads, band aids, etc.) work?**

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. Each kit, with the exception of those designated for use with the Pfizer vaccine, will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit

Additionally, for vaccines that require mixing with an adjuvant, a mixing kit sufficient to support 100 doses will include:

- Needles, 11 19-21G x 1.5” per kit
- Syringes, 11 5ml or 6ml per kit
- Alcohol prep pads, 22 per kit

The Pfizer vaccination kit will support 975 doses to match the shipping unit associated with the Pfizer vaccine:

- Needles, 1,026 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 1ml, 1026 per kit
- Needles (for mixing), 205 per kit (21-25G x 1.5”)
- Syringes (for mixing), 205 per kit (3ml or 5ml)
- Alcohol prep pads, 2458 per kit
- 40 surgical masks and 20 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 1000, per kit
- Diluent, sufficient to mix 1,000 doses

**16. Will there be further guidance documents on handling ultra-cold vaccine (i.e. thawing, storage after thawing, reconstitution, etc.?)**

OWS is working with manufacturers to ensure educational materials for providers and pharmacists, including information on proper handling, will be distributed to all jurisdictions and Federal entities. These materials will include graphic depictions for safe storage and administration temperature maintenance protocol requirements. General guidance on ultra-cold vaccine is already included in the CDC’s *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*.

**17. We are aware of concerns that there is already a shortage of dry ice, which is being used to store the ultracold storage vaccines during the clinical trials.**

**If that is true, does that shortage impact plans for shipping of ultracold storage vaccine using dry ice and containers that could store the vaccine for up to a week?**

**If there is a shortage of dry ice, does this change the guidance to states to not purchase additional ultracold storage freezers?**

National assessment of dry ice production capacity indicate that while capacity is sufficient broadly, less populated / rural areas more distant from production and distribution centers may experience difficulty attaining dry ice. The OWS/CDC is exploring options to resolve this, to include possible reliance upon Ultra Low Temperature (ULT) freezers at administration sites, and solutions to provide increased access to dry ice. Because of the local nature of the dry ice supply chain, it’s essential that states and territories assess and engage with local dry ice

suppliers, and/or select administration sites capable of ULT. We welcome governors along with other state, local, and tribal officials' input and best practices.

**18. We also need guidance on redistribution of ultracold storage vaccines. If they will come in 1,000 dose shipments as indicated by the federal government, we likely will need to distribute them further in our rural areas. What will the guidelines be to do that without compromising the vaccine?**

Further guidance will be released concerning ultracold chain storage and distribution based on the refined plans being developed. Solutions will be provided in partnership with the vaccine manufacturer. We welcome governors along with other state, local, and tribal officials' input and best practices.

**19. How long will the product be viable outside of the original packaging that the 1,000 doses will be shipped in? Can/will smaller volume packaging be provided in the shipment as well?**

Per the manufacturer, there is ongoing work to develop smaller package sizes for distribution of vaccine shipments. HHS/OWS continues to work with vaccine developers to confirm stability data and extend the available safe administration windows. General guidance on ultra-cold vaccine is already included in the CDC's *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*.

**20. What will the federal guidance be on sub-prioritization among the initial priority groups since there will not be enough vaccine at first for even healthcare workers as a group?**

In the initial phase, or Phase 1, of the COVID-19 Vaccination Program, limited availability of initial doses of vaccine will be distributed based on allocation data mutually confirmed between the jurisdiction and CDC. During limited availability, the prioritization plan approved at the federal level has the goal of protecting essential workers and the most vulnerable elderly populations. Secondary goals include maximizing public health protection while minimizing waste and inefficiency. Jurisdictions should prioritize enrollment activities for vaccination providers who will administer COVID-19 vaccine to the populations of focus for Phase 1, giving consideration to those who live in remote, rural areas and may have difficulty accessing vaccination services. Simultaneously, jurisdictions should develop operational procedures for temporary or mobile clinics planned for Phase 1 prior to receipt of vaccine.

### C. Communication and Information Requirements

**21. There has been some indication that large pharmacy chains and possibly interstate healthcare systems will register directly with the federal government. We need the specific details since many of them are also reaching out to the states. This affects our targeted enrollment of these stakeholders to onboard as Covid-19 vaccine providers. When can we expect clarification on which stakeholders will contract directly with the federal government?**

HHS is partnering with Walgreens and CVS to offer on-site COVID-19 vaccination services for nursing homes and assisted living facilities. The Pharmacy Partnership for Long-term Care (LTC) Program provides end-to-end management of the COVID-19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments.

In addition, HHS is also partnering with retail chain pharmacies and networks of community pharmacists in the United States (U.S.) will increase access for the general population to the COVID-19 vaccine. To date, 12 partners have enrolled, comprising over 55% of the nation's pharmacy network. Through this program, select pharmacy partners will receive a direct allocation of COVID-19 vaccine. This will help jurisdictions augment access for the general public when supply increases and vaccine recommendations are beyond the initial critical populations.

No additional commercial partners have been brought on board to receive federal allocations of vaccine.

**22. Will there be coordinated multi-state process for monitoring vaccination effects (adverse effects, lack of immunity responses, etc.) to ensure early warning signs are identified as quickly as possible?**

A three-pronged national approach will monitor vaccines safety after administration and communicate safety information.

- Use established systems to implement heightened safety monitoring for COVID-19 vaccines
- Develop new platforms and leverage other federal data sources to complement existing systems
- Communicate clearly on the vaccine safety process and systems now; provide COVID-19 vaccine safety data and monitoring results once available.

Many of the systems that will be used are existing safety platforms. The Vaccine Adverse Event Reporting System (VAERS) is available to healthcare providers to report adverse health events in patients following vaccination. Additional systems are being developed to complement existing systems-

**23. Will the federal government provide current/real time information about tribal nations enrolling with the CDC for direct shipments, versus enrolling through the state?**

Currently, tribal nations have until October 30, 2020 to inform the states or IHS whether they will directly enroll to receive vaccine or whether they go through the state. This information will be shared with the state to ensure that state allocations are consistent with projections. OWS has incorporated liaison officers from each of the Federal entities as well as the IHS and others in the vaccine operations center at HHS to ensure close coordination throughout distribution planning and execution.

**24. Can the administration provide more information around long term care facilities? Specifically, are they planning to mandate vaccines in nursing homes through CMS? For example, will the use of vaccines be connected to continued Medicaid funding? If so, when would such requirements take effect?**

To support public transparency of vaccine utilization across different health care settings, including nursing homes, CMS is actively considering vaccine reporting requirements and quality measures for both staff and patients or residents. CMS will be releasing more information in the coming weeks as part of its broader strategy to support COVID-19 vaccine uptake.

**25. Is the federal government going to request that states report personally identifiable COVID vaccine data? We have concerns that this may create a lack of trust and discourage people from getting vaccinated.**

In order to accurately and effectively track the administration of the COVID-19 vaccine from several data sources including jurisdiction immunization information systems, it is necessary to collect personally identifiable data from vaccine recipients. This is critically necessary to ensure:

- Matching the correct second dose to the correct patient, ensuring that both dose number and product are consistent with eventual guidance from the ACIP
- Creating an accurate accounting of administration of vaccines being reported by multiple sources of data
- Identifying vaccine and patient information in the event of adverse events to address safety issues
- Assessing the effectiveness of the vaccine among different demographic groups within the population

Identifiable data will not be available to CDC or other federal agencies for programmatic use and will only be used to track and reconcile COVID-19 vaccine administration data from disparate data sources. CDC is exploring solutions that allow information exchange on vaccine administration, while preserving and protecting PII and PHI.

## **26. What is the state’s role in safety monitoring after people have been vaccinated?**

The state may or may not have a role in safety monitoring after a vaccine is administered. It is dependent on the vaccination planning that has been conducted by the state. The federal government has a multi-faceted approach for ensuring safety after administration. Many of the systems that will be used are existing safety platforms that have been used regularly by providers. Some additional systems are being developed to ensure broad ability to report any adverse health events.

## **27. How many states are using Vaccine Administration Management System (VAMS) as their Immunization Information System (IIS)?**

As of October 28, 2020 there are 12 jurisdictions on-boarding to the VAMS application with numerous other showing interest and beginning coordination with the CDC.

## **28. Will states share their micro-prioritization within Phase 1b?**

States are welcome to share their microplans with whomever they choose and, as of October 28, 2020, 46 of the 50 states have publicly released the vaccine distribution plans submitted to the CDC on October 16. Four states (AL, DE, NH, and SD) have not, along with DC.

The CDC will be posting executive summaries of the submitted plans to ensure transparency, while recognizing that some parts of the plan are iterative.

## **29. What communication/messaging materials have been developed?**

Regarding a COVID-19 vaccine, it is important to educate the public on the rigorous FDA vaccine review process. Toward that end, there are materials that explain the vaccine development process in layman’s terms at the FDA website.

- <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process>

In addition, with regard to the safety and efficacy of a COVID-19 vaccine, there is an August 18, 2020 Health Affairs article by FDA Commissioner Dr. Stephen Hahn, FDA Director for the Center for Biologics Evaluation and Research (CBER) Dr. Peter Marks, and Deputy Commissioner for Medical and Scientific Affairs, Dr. Anand Shah on “Ensuring the Safety and Effectiveness of a COVID-19 Vaccine” which outlines safeguards that exist in the approval process.

- <https://www.healthaffairs.org/doi/10.1377/hblog20200814.996612/full/>

Additionally, multiple efforts to educate the public on the FDA application, review, and approval process for a COVID-19 vaccine are ongoing through op-eds and public appearances by FDA and Administration leadership.

CDC has launched Vaccinate with Confidence, a strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the U.S. This program will

be updated with information on the COVID-19 vaccines as it becomes available, and resources will be shared with partners. CDC also will continue to update its COVID-19 vaccine website with information for states, providers, healthcare workers, and the general public.

- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

CMS is launching a vaccine information portal for providers, health plans and issuers, and states and territories. The portal is designed to support providers, health plans and issuers, and states as we all work to ensure broad access to COVID-19 vaccines for all Americans, and will include fact sheets, vaccine toolkits, and partner info.

The FDA is providing messaging on vaccines generally via a campaign #FDAVaccineFacts on Social Media.

In terms of messaging and materials to explain a specific FDA-approved COVID-19 vaccine, that will need to be prepared when more is known about the specific characteristics and guidelines on that vaccine.

### **30. How will complex scientific data be messaged and shared publicly? What type of educational material, and in what languages, will be developed?**

Throughout the pandemic, materials for the general public explaining the COVID-19 virus and providing guidance have been made available and updated on multiple government landing pages and websites, including those found at:

- Federal Government - <https://www.coronavirus.gov/>
- HHS - <https://www.hhs.gov/coronavirus/index.html>
- CDC - <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- FDA - <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>
- NIH - <https://www.nih.gov/coronavirus>
- Operation Warp Speed – <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>

An example of translating complex scientific data and sharing it publicly is the simple mitigation message of the “3 Ws” (1) Wash your hands, (2) Wear a Mask, and (3) Wait six feet apart.

Looking forward to educating the public about a COVID-19 vaccine, we expect all of these channels will be employed. Materials will be made available for the general public, but also targeted communication materials and outreach for key populations like healthcare providers, seniors, and racial and ethnic minorities will also be supported.

HHS and its agencies will continue to provide the public access to their experts to brief the public and inform the media, general public, and various stakeholders.

Any materials from HHS will be reviewed by the appropriate scientific and public health experts.

In addition to federal level communication efforts, states will also be provided funding to support communication outreach.

### **What type of educational material, and in what languages, will be developed?**

The Administration, HHS, and its operating divisions are rolling out educational material as information becomes available.

HHS and Operation Warp Speed has released materials related to the process of Operation Warp Speed to help educate the public. These include videos, infographics, and fact sheets.

Currently, there is not a great deal of final information about any of the individual vaccines. But HHS and CDC have long worked to promote vaccine confidence, and have resources in multiple languages.

#### CDC Coronavirus Vaccines

- [8 Things to Know about Vaccine Planning](#)
- [How CDC Is Making COVID-19 Vaccine Recommendations](#)
- [Ensuring the Safety of COVID-19 Vaccines in the United States](#)
- [Frequently Asked Questions about COVID-19 Vaccination](#)

#### Coronavirus (COVID-19) | CBER-Regulated Biologics

#### COVID-19 Prevention Network (CoVPN) FAQ about Covid-19 Vaccine Development

#### NIH COVID-19 Communities Responding Together

- [Get the latest research information from NIH](#)
- [Get the latest public health information from CDC](#)
- [See NHLBI information & resources on COVID-19](#)
- [Find trials in the CoVPN](#)
- [Read more about NIAID's COVID-19 clinical research](#)
- [Find NIMHD information and resources on COVID-19](#)

#### CDC Vaccines & Immunizations

- [Vaccine Information Statements \(VIS\)](#)
- [Immunization Schedules](#)
- [Side Effects](#)
- [Basic and Common Questions](#)
- [Vaccines and Preventable Diseases](#)

#### FDA Vaccines

- [Biologics License Applications \(BLA\) Process \(CBER\)](#)
- [CDC National Immunization Program](#)
- [Questions about Vaccines](#)
- [Vaccines and Related Biological Products Advisory Committee](#)
- [Vaccine and Related Biological Product Guidances](#)
- [Common Ingredients in U.S. Licensed Vaccines](#)
- [Vaccine Adverse Events](#)
- [Vaccine Safety & Availability](#)
- [HHS Vaccines and Immunizations](#)

CDC has launched [Vaccinate with Confidence](#), a strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the U.S. This program will be updated with information on the specifically approved COVID-19 vaccines as it becomes

available, and resources will be shared with partners. CDC also will continue to update its COVID-19 vaccine website with information for states, providers, healthcare workers, and the general public.

- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>. This information is available in multiple languages.

CMS is launching a vaccine information portal for providers, health plans and issuers, and states and territories. The portal is designed to support providers, health plans and issuers, and states as we all work to ensure broad access to COVID-19 vaccines for all Americans, and will include fact sheets, vaccine toolkits, and partner info.

### **31. What information will be shared publicly on each approved vaccine? How will transparency be ensured?**

At every stage of this process, the Administration is committed to following long-established review processes which involve transparency, independent review, and rely on the assessments of career scientists at the FDA.

Already, FDA has provided a high degree of transparency by outlining safety and efficacy criteria the FDA would expect from vaccine developers for approval of any vaccine through two guidance documents.

In initial guidance published in June 2020 and additional formal guidance released in October, the agency reaffirmed its commitment to long-held gold standards for assessing vaccine safety and efficacy. The agency affirmed an “EUA-plus” standard to the review of potential COVID-19 vaccines that will require vaccine manufacturers to demonstrate safety and efficacy for an EUA similar to that expected during the review of a full BLA request.

In addition, at multiple junctures in the vaccine review process, independent advisory bodies are involved and offer transparency with opportunities for public participation, viewing of the proceedings, and access to materials shared with and by advisory members. These advisory bodies, which operate under the Federal Advisory Committee Act (FACA), have public meetings to allow public observance and comment on discussion.

- Vaccine Product Approval Process: <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process>
- Information on Data Safety Monitoring Boards: <https://www.nidcr.nih.gov/research/human-subjects-research/toolkit-and-education-materials/interventional-studies/data-and-safety-monitoring-board-guidelines>
- Vaccines and Related Biological Products Advisory Committee: <https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee>
- Advisory Committee on Immunization Practices: <https://www.cdc.gov/vaccines/hcp/conversations/acip-recommendations.html>

**32. CDC is planning to require reporting to the IIS within 24 hours of administration of the vaccine. We know for flu vaccine there is a dramatic lag in data coming in – how will COVID-19 vaccine data reporting be any different?**

IIS will be required to report information on COVID-19 vaccine data elements in a timely fashion and through a connection to the Immunization Gateway (IZ Gateway) or data lake. This will enable CDC to reliably track COVID-19 vaccinations and analyze vaccination coverage by demographic factors once vaccine supplies are available. These requirements are outlined in the provider enrollment agreement. The reporting requirements for COVID-19 are more stringent than those for flu to ensure more timely reporting.