February 10, 2021

Dear Tribal Leaders, Public Health Officials, and Indian Country Professionals:

Last week, Janssen Biotech Inc., a division of Johnson and Johnson, submitted an emergency use authorization (EUA) application for a COVID-19 vaccine. The Food and Drug Administration (FDA) is reviewing the application, and will make recommendations to the Commissioner of Food and Drugs on the authorization of the Janssen product after careful review and public deliberation through the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The FDA has scheduled a VRBPAC meeting to discuss this product for February 26, 2021. Background materials, livestream links, and more information will be posted on the FDA's VRBPAC site here. The full press release from the FDA can be found here.

Executive Actions

Members of the Biden-Harris Administration COVID-19 Health Equity Task Force Announced: Today, President Biden and Vice President Harris announced the following individuals to serve as non-federal members of the Biden-Harris COVID-19 Health Equity Task Force. To help ensure an equitable response to the pandemic, the President signed an executive order on January 21 creating a task force to address COVID-19 related health and social inequities. This Task Force is chaired by Dr. Marcella Nunez-Smith.

Launch of Community Health Centers Vaccination Program: The President announced next week's launch of the Federally Qualified Health Center Vaccine program that will provide more vaccines for Community Health Centers that are reaching our underserved and most vulnerable communities. The program will be phased in, with the first centers able to start ordering vaccines as early as the week of February 15. The initial phase will include at least one Community Health Center in each state, expanding to 250 centers in the coming weeks.

Additional Increase in Vaccine Supply to States, Tribes and Territories: The Biden-Harris Administration will increase overall, weekly vaccine supply to states, Tribes, and territories to 11 million doses nationwide beginning this week. This will result in a 5% increase in supply over last week, for a total of a 28% increase since President Biden came into office three weeks ago.

Maximizing Assistance from FEMA to Provide Additional Funding and Support to States: The White House released a memo on Maximizing Assistance from the Federal Emergency Management Agency. President Biden noted that "it is the policy of my Administration to combat and respond to COVID-19 with the full capacity and capability of the Federal Government to protect and support our families, schools, and businesses, and to assist State, local, Tribal, and territorial governments to do the same, including through emergency and disaster assistance available from the Federal Emergency Management Agency (FEMA)." As part of the memo, states, Territories and tribes will be fully reimbursed retroactively from January 20, 2020 and going forward for FEMA-eligible services — including

masks, gloves, emergency feeding actions, sheltering at risk populations, and mobilization of the National Guard.

Additional Details on Increasing Vaccine Supply, Initial Launch of the Federal Retail Pharmacy Program, and Expansion of FEMA Reimbursement to States: The Biden Administration released a Fact Sheet on the additional steps announced last week to implement his comprehensive National Strategy to combat the COVID-19 pandemic. These steps include increasing the vaccine supply to states, Tribes, and territories to 10.5 million doses nationwide and securing the equipment to extract a 6th dose from Pfizer's vials, and increasing funding to jurisdictions to help turn vaccines into vaccinations. And, the President announced that starting this week on February 11, the first phase of the federal pharmacy program will launch and select pharmacies nationwide will start offering vaccinations for their communities.

State Profile Reports: HHS and the White House COVID-19 response team have released the <u>weekly</u> <u>state profile snapshot</u>. The purpose of this report is to develop a shared understanding of the current status of the pandemic at the national, regional, state, and local levels.

Strengthening Americans' Access to Quality, Affordable Health Care: President Biden signed an Executive Order that will begin to restore and strengthen Americans' access to quality, affordable health care. View the fact sheet about this executive order here. As part of the order, the Biden-Harris Administration will open a Marketplace Special Enrollment Period for COVID-19 Public Health Emergency for Americans to sign up for health coverage. This SEP will allow individuals and families in states with Marketplaces served by the HealthCare.gov platform to enroll in 2021 health insurance coverage. Beginning February 15, 2021 and through May 15, 2021, these Marketplaces will operationalize functionality to make this SEP available to all Marketplace-eligible consumers who are submitting a new application or updating an existing application. The Executive Order also includes a provision for agencies to policies or practices that may undermine protections for people with preexisting conditions, including complications related to COVID-19, under the ACA.

HHS Departmental Updates

IHS Update: The IHS <u>announced the allocation decisions for \$1 billion</u> recently received by the agency in additional COVID-19 funding to respond to the coronavirus pandemic. Of the \$1 billion provided in the act, \$790 million will support testing, contact tracing, containment, mitigation, and related activities to monitor and suppress COVID-19 in American Indian and Alaska Native communities. The bill also provides \$210 million for IHS, tribal, and urban Indian health programs to plan and prepare for coronavirus vaccines to ensure broad-based distribution, access, and vaccine coverage.

Also last week, the IHS announced that it would receive a supplemental supply of 130,000 vaccines this week to distribute to federal, tribal and urban Indian health care programs. This is in addition to the regular weekly allocation. IHS will continue to ensure that tribal communities have equitable access to safe and effective vaccines. While vaccines are an important tool in helping to stop this pandemic, it will

take time to deliver and administer the vaccine to everyone who needs it. The COVID-19 vaccine is the safest, most effective and most reliable way to keep yourself, your family and your community healthy. As of February 9, the IHS has administered more than 297,375 total COVID-19 doses, this includes 219,484 individual COVID-19 vaccine first doses and 73,708 individual COVID-19 second doses, overall 60% of the 492,875 COVID-19 vaccines that were shipped to IHS facilities have been administered.

Information on the number of COVID-19 vaccines administered across the Indian Health Service can be found at <a href="https://covid.cdc.gov/covid-data-tracker/#vaccinationshttps://covid.cdc.gov/covid-data-track

ACL Update: The Coronavirus Response & Relief Supplemental Appropriations Act of 2021 provided ACL \$275 million to be allotted to three categories:

- \$168 million for Nutrition Services under the authority of Title III-C-2 of the Older Americans Act;
- \$7 million for Native American Nutrition and Supportive Services under the authority of Title VI,
 Parts A&B of the Older Americans Act; and
- \$100 million in first-time direct funding for Elder Justice Activities/Adult Protective Services under the authorities of the Elder Justice Act.
 - These funds will allow ACL, States, Territories, and Tribes additional abilities to offer supports aligned with the goals of enhancing community living during the COVID-19 pandemic. Recently, ACL awarded the \$175 million for Nutrition Services and Native American Nutrition and Supportive Services to enhance ongoing community efforts begun with the support of previous COVID-19 supplemental appropriations. Tables showing the nutrition awards are available at acl.gov/about-acl/budget.

ACF Update: On February 3, the Administration for Children and Families (ACF) awarded nearly \$10 billion in supplemental Child Care and Development Fund (CCDF) program funding to states, territories, and Tribes to address the needs of child care providers and families resulting from the coronavirus disease 2019 (COVID-19) pandemic. These funds were made available under the recently enacted Consolidated Appropriations Act of 2021 and Coronavirus Response and Relief Supplemental Appropriations (CRRSA) Act of 2021 (P.L. 116-260). Tribes will be receiving \$275,000,000 of the CRRSA funds. More information on the use of these funds, including reporting requirements, can be found through the OCC COVID-19 Resources page.

CDC Update: The Centers for Disease Control and Prevention (CDC) has updated their budget, grants, and funding webpage with information on <u>CDC COVID-19 Funding for Tribes</u>.

Vaccine Updates

Resources: CDC updated their resource page on <u>COVID-19 vaccinations</u>. On this page you can find the benefits of the vaccine, community mitigation framework, toolkits, and more.

Data Tracker: If you want to keep track of the vaccine progress in your state over the coming weeks, it's now pretty easy to do online at the <u>Centers for Disease Control and Prevention (CDC) COVID Data Tracker</u>. It offers an interactive state-by-state map, as well as data on vaccinations in long-term care facilities. Please note that there's a delay of three to five days in reporting actual vaccinations from the states.

Vaccine Data Collaboration: CDC COVID Data Tracker recently launched the <u>vaccinations trends page</u>. This page includes the overall trends of vaccinations over time in the US and for the Federal Pharmacy Partnership for Long-Term Care (LTC) Program. Data shown include the total number of doses administered and number of people receiving doses of vaccine for the United States. We also show these for the Federal Pharmacy Partnership for Long-Term Care (LTC) Program, which is a subset of the United States total.

Toolkits: CMS released a COVID-19 Provider Toolkit to ensure health care providers have the necessary tools to respond to the COVID-19 public health emergency. The toolkit includes information on:

- How health care providers can enroll in Medicare to bill for administering COVID-19 vaccines
- The COVID-19 vaccine Medicare coding structure;
- The Medicare payment strategy for COVID-19 vaccine administration;
- How health care providers can <u>bill correctly for administering vaccines</u>, including roster and centralized billing;
- Monoclonal antibody infusion for treating COVID-19; and
- New COVID-19 Treatments Add-on Payment (NCTAP)

You can also review the set of <u>COVID-19 FAQs</u>, which has information specific to health care providers who bill Medicare for administering COVID-19 vaccines.

Building Vaccine Confidence: Many factors influence vaccine decision-making, including cultural, social, and political factors; individual and group factors; and vaccine-specific factors. However, confidence in the vaccines, the vaccinator, and the system all support the decision to get vaccinated. The CDC Vaccine Task Force has online tips for building vaccine confidence.

Explaining Community Immunity: When enough of the <u>community is immunized against a contagious disease</u>, most other members are protected from infection because there's little opportunity for the disease to spread.

COVID-19 Variants: CDC updated their information about the <u>characteristics of the variants</u>, with information rapidly emerging. Scientists are working to learn more about how easily they spread, whether they could cause more severe illness, and whether currently authorized vaccines will protect people against them. Find more information about variant cases and where they are in the US <u>here</u>.

FDA Continues Important Work to Support Medical Product Development to Address New Virus Variants: Since the beginning of the pandemic, FDA has anticipated the possible emergence of coronavirus variants. They have been actively assessing the impact of new strains on authorized products and continue to work with medical product sponsors and international partners to evaluate the impact that each variant may have on effectiveness or utility of authorized medical products. FDA has already been communicating with individual medical product sponsors to provide information as they evaluate the impact of COVID-19 variants on their products. And as part of FDA's commitment to a public and transparent process, FDA is developing guidance for diagnostic, therapeutic and vaccine developers to help guide ongoing medical product development. To read the entire statement from FDA's Acting Commissioner, Janet Woodcock, M.D., click here.

FEMA Releases Community Vaccination Playbook: As part of the national effort to speed the pace of COVID-19 vaccination campaigns, the president directed the federal government to establish new federally supported Community Vaccination Centers (CVCs). <u>This playbook</u> establishes guidance for providing federal support to existing and new CVCs including interagency coordination, resource support, facility setup, and other requirements that necessitate federal support.

Other Events of Interest

The National Telecommunications and Information Administration (NTIA) is holding Tribal Consultations for input on implementation of the Tribal Broadband Connectivity Program (TBCP). The Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 (Act), provides new sources of tribal broadband funding that can assist in mitigating the effects of the COVID-19 pandemic exacerbating the digital divide across Indian Country. The Department of Commerce and NTIA are dedicated to expanding broadband deployment in unserved areas and promoting digital inclusion. Please review this link regarding Tribal Consultations occurring in February, 2021, on the Tribal Broadband Connectivity Program: https://broadbandusa.ntia.doc.gov/ntia-event/tribal-broadband-connectivity-program-tribal-consultations#contententarea

The IHS and Smithsonian's National Museum of the American Indian invite you to participate in an important discussion about combating COVID-19 in Indian Country on Thursday, February 11, 2:00 p.m. – 3:30 p.m. EST. The event will feature IHS Chief Medical Officer Dr. Michael Toedt, IHS Navajo Area Chief Medical Officer Dr. Loretta Christensen, and Great Lakes Area Tribal Health Board Chair Phyllis Davis. The program will be moderated by Dr. Charles Grim, Chickasaw Nation secretary of health and former IHS director. COVID-19 has had a disproportionate impact on Native communities throughout the United States. Join health experts for a conversation about COVID-19 and its impact in Indian Country. Please register for this event using the following link: Registration Link.

Resources

- HHS COVID Education Campaign page
- CMS COVID-19 Partner Resources Page
- CDC's national and global response
- CDC FAQs on COVID-19
- CDC Updated Information on COVID-19 for healthcare workers
- CDC Updated Resources on travel
- CDC Toolkit for Essential Workers
- CDC Toolkit for Community-Based Organizations
- CDC Resources for Facility Planning and Operations
- CDC Resources for Surge Mitigation
- CDC Resources for Exposure in Healthcare Settings
- CDC Updated Critical Infrastructure Guidance
- CDC Updated Resources on Masks
- CDC guidance for agricultural workers and employers
- CDC Updated Information for school nurses and other healthcare personnel
- CDC Readiness and planning tool for primary and secondary schools in low resource settings
- CDC Updated Resources for pregnant people, breastfeeding people and new parents
- CDC Updated guidance on small gatherings
- CDC Updated guidance on large gathering
- FDA Updated Fact Sheet for Health Care Providers on the use of convalescent plasma

Please don't hesitate to contact us if you have any questions!

Tribal Affairs Team

Office of the Secretary | Intergovernmental and External Affairs Department of Health and Human Services