August 18, 2021

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

Today, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released a statement on the Administration's plan for COVID-19 booster shots for the American people.

"The COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant. Recognizing that many vaccines are associated with a reduction in protection over time, and acknowledging that additional vaccine doses could be needed to provide long lasting protection, we have been analyzing the scientific data closely from the United States and around the world to understand how long this protection will last and how we might maximize this protection. The available data make very clear that protection against SARS-CoV-2 infection begins to decrease over time following the initial doses of vaccination, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease. Based on our latest assessment, the current protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who are at higher risk or were vaccinated during the earlier phases of the vaccination rollout. For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection and prolong its durability."

"We have developed a plan to begin offering these booster shots this fall subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and CDC's Advisory Committee on Immunization Practices (ACIP) issuing booster dose recommendations based on a thorough review of the evidence. We are prepared to offer booster shots for all Americans beginning the week of September 20 and starting 8 months after an individual's second dose. At that time, the individuals who were fully vaccinated earliest in the vaccination rollout, including many health care providers, nursing home residents, and other seniors, will likely be eligible for a booster. We would also begin efforts to deliver booster shots directly to residents of long-term care facilities at that time, given the distribution of vaccines to this population early in the vaccine rollout and the continued increased risk that COVID-19 poses to them."

Read the Full Statement and Press Release here.

HHS Tribal Consultation Updates

Tribal Consultation on IHS Mandatory Funding: Last week, U.S. Department of Health and Human Services Secretary Xavier Becerra <u>initiated Tribal Consultation</u> to seek input and recommendations on mandatory funding approaches for the Indian Health Service (IHS). The fiscal year (FY) 2022 President's Budget commits to conducting robust Tribal Consultation and Urban Confer to evaluate options, including mandatory funding, to provide adequate, stable, and predictable funding for the IHS in the future.

There are two virtual Tribal Consultations Tribal Leaders are invited to attend to share input and recommendations on mandatory funding approaches and to discuss these important questions as well as hear any thoughts and concerns, no registration necessary.

<u>Wednesday, August 25, 2021</u> 1:00 – 4:00 PM ET <u>Zoom Link</u>

Wednesday, September 1, 2021 2:00 – 5:00 PM ET Zoom Link

In addition, if you would like to submit written comments and recommendations on the mandatory funding approaches, please submit comments by **Friday, September 3, 2021**. You can submit written comments via email at <u>consultation@hhs.gov</u>.

IHS Urban Confer on IHS Mandatory Funding: To complement the HHS Tribal Consultation on Mandatory Funding for IHS, the <u>IHS initiated Urban Confer</u>. Urban Indian Organization Leaders are invited to a virtual Urban Confer session to share input and recommendations on mandatory funding approaches for IHS.

<u>Monday, August 30, 2021</u> 2:00 – 4:00 PM ET <u>Zoom Link</u>

Administration for Children and Families (ACF) Office of Head Start (OHS): The OHS has scheduled three Tribal Consultation sessions. These one-day sessions will be held between HHS, ACF, and OHS leadership and the leadership of tribal governments operating Head Start and Early Head Start programs. The purpose of these consultation sessions is to discuss ways to better meet the needs of American Indian and Alaska Native (AIAN) children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. The dates of the virtual sessions are included below:

- Geographic Regions 6–8: Wednesday, August 18, 2021, 1–4 p.m. ET
- Geographic Regions 9–10: Tuesday, September 21, 2021, 2–5 p.m. ET
- National: Monday, November 15, 2021, 1–4 p.m. ET

Additional information can be found on the <u>ELCKC website</u>. To register, <u>click here</u>.

Departmental Updates

Secretary Becerra to Require COVID-19 Vaccinations for HHS Health Care Workforce: To increase vaccination coverage and protect more people from COVID-19, including the more

transmissible Delta variant, <u>HHS will require more than 25,000 members of its health care</u> <u>workforce to be vaccinated against COVID-19</u>. Staff at the Indian Health Service (IHS) and National Institutes of Health (NIH) who serve in federally-operated health care and clinical research facilities and interact with, or have the potential to come into contact with, patients will be required to receive the COVID-19 vaccine. This includes employees, contractors, trainees, and volunteers whose duties put them in contact or potential contact with patients at an HHS medical or clinical research facility. Additionally, U.S. Surgeon General Dr. Vivek Murthy will immediately require members of the U.S. Public Health Service Commissioned Corps to be vaccinated against COVID-19 as part of medical readiness procedures to prepare for any potential deployment need as emergency responders.

COVID-19 Immunizations Requirements for Personnel Working in IHS Health Care Facilities: IHS <u>released a Special General Memorandum (SGM)</u> to establish IHS requirement for COVID-19 immunizations for all personnel working in an IHS health care facility. IHS also <u>released a</u> <u>COVID-19 vaccine requirement Q&A page</u>.

Symposium on Missing and Murdered Indigenous Peoples: HHS along with the Departments of Justice and Interior are committed to working with Tribes across the country who need and deserve federal resources to bring answers and justice to communities affected by Missing and Murdered American Indians and Alaska Natives. In an effort to find lasting solutions to the public safety challenges Tribal communities encounter and to protect them from violence, abuse, and exploitation, a national symposium on missing or murdered indigenous persons (MMIP) related issues for federal, state, tribal and local stakeholders is being held September 14-16, 2021. This MMIP training is via webinar and will address important topics like data collection, victim advocacy, creating a community strategy for addressing missing persons, and working collaboratively across jurisdictions. The webinar is free.

Register for the Symposium on Missing or Murdered American Indians and Alaska Natives. Registration Deadline: **Friday, September 10, 2021**

Indian Health Service Update (IHS): The IHS continues to focus on administering as many COVID-19 vaccines as possible. The IHS reached another milestone -- more than 1.5 million vaccine doses to patients, employees, and tribal and urban community members. Over 57 percent of American Indian and Alaska Native adult patients have received at least one vaccine dose, and approximately 48 percent have been fully vaccinated. More than 15,000 of our American Indian and Alaska Native adolescents between the ages of 12 and 15 are fully vaccinated.

The IHS invites you to join the following events:

 <u>August 17-20, 2021: 16th Annual Government-to-Government Violence Against Women</u> <u>Tribal Consultation</u> - The consultation is held pursuant to Section 903 of the Violence Against Women and Department of Justice Reauthorization Act of 2005 (codified as amended at 34 U.S.C. § 20126).

- <u>Thursday</u>, August 19, 2021 at 1:00 2:30 PM ET: 2021 National Combined Councils <u>Virtual Conference</u>: Day 2 - Building Community Within IHS: Strategies to Create a <u>People-Centered Workplace</u>
- Thursday, August 19, 2021 at 3:00 4:00 PM ET: August All Tribal and Urban Indian Organization Leaders Call
- <u>Tuesday</u>, <u>August 24</u>, 2021 at 3:00 4:30 PM ET: IHS Directors Advisory Committee on <u>Tribal Consultation</u>
- <u>Thursday, August 26, 2021 at 1:00 2:30 PM ET: 2021 National Combined Councils</u> <u>Virtual Conference: Day 3 - Team-based Approaches to Safe Opioid Prescribing</u>
- <u>Thursday</u>, August 26, 2021 at 12:00 4:30 PM ET: IHS Direct Service Tribes Advisory <u>Committee</u>
- Friday, August 27, 2021 at 1:00 4:00 PM ET: Tribal Consultation The IHS and the U.S. Department of the Interior's Office of the Assistant Secretary Indian Affairs invite you to consult on Indian Self-Determination and Education Assistance Act section 105(*I*) lease requirements and payments, with a goal toward consistent and transparent 105(*I*) lease administration. For additional details, please refer to the letter sent to Tribal Leaders on July 27, 2021 [PDF 240 KB].

Centers for Disease Control and Prevention (CDC): CDC <u>updated their information on non-</u> <u>emergency transportation for tribal communities</u>, to include digital resources.

Vaccine Updates

Additional Vaccine Dose Authorized for Certain Immunocompromised Individuals: The FDA amended the emergency use authorizations (EUAs) for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals. Specifically, this includes solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. The CDC's Advisory Committee on Immunization Practices is scheduled to meet Friday to discuss further clinical recommendations regarding immunocompromised individuals.

This action does not apply to people who are not immunocompromised. In response to the FDA's recent action that authorizes an additional dose of COVID-19 vaccine for immunocompromised individuals, <u>CMS is assuring people with Medicare who qualify for an additional dose that they can receive it with no cost sharing</u>. View information on <u>COVID-19</u> vaccines for moderately to severely immunocompromised people and learn about how to <u>talk</u> with immunocompromised patients.

Vaccination Program Operational Guidance: The CDC <u>released guidance for jurisdictions</u> <u>planning to operate COVID-19 vaccination clinics</u>. To meet vaccination goals, jurisdictions are planning for and operating multiple, temporary, large- and small-scale vaccination sites, both fixed location and mobile, as strategies to vaccinate more of the population rapidly. This guidance provides information that informs the planning and operations of all types and sizes of vaccination clinics, including key considerations to maximize throughput at vaccination sites in large venues, drive-through vaccination clinics, and smaller-scale mobile vaccination venues.

HHS Ask an Expert: FDA's vaccine expert, Dr. Peter Marks, participated in the <u>HHS Ask An</u> <u>Expert video series</u> to answer some of your most frequently asked questions about COVID-19 vaccination. <u>Test your knowledge of the COVID-19 vaccines</u>.

Vaccine Allocation Transfer and Redistribution for IHS and Tribal Facilities: <u>The vaccine</u> <u>transfer/redistribution processes outlined on this page</u> are the legal methods to adjust to changes in vaccine supply and demand. This guidance outlines two methods to transfer vaccines to IHS-operated facilities and facilities operated by Tribal Health Program and Urban Indian Organization (I/T/U) participating in the CDC COVID-19 Vaccination Program coordinated through IHS. The transfer of vaccines under these two methods eliminates the need for Tribal Health Programs and Urban Indian Organizations to sign separate CDC COVID-19 Vaccination Provider Agreements through a state/local jurisdiction.

Things to Know about COVID-19 Vaccines: A new FDA <u>Consumer Update highlights 5 Things to</u> <u>Know about COVID-19 Vaccination for Adolescents.</u> The CDC recommends COVID-19 vaccination for everyone 12 and older.

How to Engage the Arts to Build COVID-19 Vaccine Confidence: CDC <u>released information on</u> <u>how to engage the arts to build COVID-19 vaccine confidence</u>. Arts and cultural engagement can generate community demand for COVID-19 vaccines by making vaccination an accessible and socially supported choice. CDC shares field guides, resources, and examples that public health professionals, health communicators, teachers, and community organizations can use in their work to increase COVID-19 vaccination confidence and demand through the arts.

Understanding Variants: Viruses constantly change through mutation, and <u>new variants of a</u> <u>virus are expected to occur</u>. Sometimes new variants emerge and disappear. Other times, new variants persist. Multiple variants of COVID-19 have emerged in the United States. At this point, the original variant that caused the initial COVID-19 cases in January 2020 is no longer circulating as newer variants have increased. View CDC's <u>video on what you need to know</u> <u>about variants</u>. See specific information on <u>the Delta Variant</u>.

Testing, Tracing, and Treatment

Testing Strategies for SARS-CoV-2: CDC updated guidance that describes and compares <u>different types of testing strategies SARS-CoV-2</u>, including their intended use and applications,

regulatory requirements, and reporting requirements. This guidance is intended for those who offer and perform SARS-CoV-2 testing. This guidance was updated to include information for fully vaccinated people given new evidence on the B.1.617.2 (Delta) variant currently circulating in the United States.

NIH Scientists Develop Faster COVID-19 Test: Scientists at the National Institutes of Health (NIH) have <u>developed a new sample preparation method to detect SARS-Cov-2</u>. The method bypasses extraction of the virus' genetic RNA material, simplifying sample purification and potentially reducing test time and cost. The method is the result of a collaboration among researchers at the National Eye Institute (NEI), the NIH Clinical Center (CC), and the National Institute of Dental and Craniofacial Research (NIDCR).

Considerations for Case Investigation and Contact Tracing in K-12 Schools and Institutions of Higher Education: CDC <u>updated their considerations for case investigation and contact tracing</u> in educational settings. These updates include updated guidance for K–12 schools and institutions of higher education, including considerations for people fully vaccinated against <u>COVID-19</u> and situations when K–12 students are not considered <u>close contacts</u>. Learn <u>what to do if a student becomes sick or reports a new COVID-19 diagnosis at school</u>. View the <u>fact sheet on additional actions to help kids go back to school safely</u>.

Funding

SAMHSA Awards \$17.8 Million in COVID-19 Funds for Suicide Prevention: The Substance Abuse and Mental Health Services Administration (SAMHSA) <u>has released 26 grant awards</u> <u>totaling \$17.8 million</u> to help communities prevent suicide during the COVID-19 pandemic. The Emergency Response for Suicide Prevention Grants program helps states, tribes and communities advance efforts to prevent suicide and suicide attempts among adults 25 and older in order to reduce the overall suicide rate and the number of suicides in the United States.

Research

COVID-19 Science Update: On Friday, CDC <u>released their COVID-19 Science Update</u>. This week's issue includes, but is not limited to, research on the following: <u>exponential growth, high</u> <u>prevalence of SARS-CoV-2 and vaccine effectiveness associated with Delta variant, vaccinated</u> <u>and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant, and outbreaks of COVID-19 variants in US prisons</u>.

COVID-19 Vaccination Safe for Pregnant People: CDC <u>released new data on the safety of the</u> <u>COVID-19 vaccines in pregnant people</u> and is recommending all people 12 years of age and older get vaccinated against COVID-19. "CDC encourages all pregnant people or people who are thinking about becoming pregnant and those breastfeeding to get vaccinated to protect themselves from COVID-19," said CDC Director Dr. Rochelle Walensky. COVID-19 vaccination is recommended for everyone 12 years of age and older, <u>including people who are trying to get</u> pregnant now or might become pregnant in the future, as well as their partners. View information on extra precautions for pregnant people. View monitoring systems for pregnant people. Find more about pregnancy or breastfeeding and COVID-19. View information on investigating the impact of COVID-19 during pregnancy

NIH Launches Study of Third COVID-19 Vaccine Dose in Kidney Transplant Recipients: A pilot study has begun to assess the antibody response to a third dose of an authorized COVID-19 <u>mRNA vaccine in kidney transplant recipients</u> who did not respond to two doses of the Moderna or Pfizer-BioNTech COVID-19 vaccine. The Phase 2 trial is sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

A Potential Home Treatment for COVID-19: Researchers at NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) have identified a potential <u>new treatment for COVID-19</u> — TEMPOL — that can be taken orally and may stop the replication of SARS-CoV-2, the virus that causes COVID-19. This treatment would likely prevent severe disease. Just as humans need minerals in their diet, researchers found that SARS-CoV-2 needs clusters of iron and sulfur minerals to replicate in cells. TEMPOL breaks up these clusters and stops the virus from multiplying. This action might prevent severe COVID-19. A clinical trial will test the ability of TEMPOL to reduce hospitalizations for people with COVID-19.

Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients: CDC released an *MMWR* on the <u>use of COVID-19 vaccines after reports of adverse events among adult recipients of Jassen and mRNA COVID-19 vaccines</u>. Rare serious adverse events have been reported after COVID-19 vaccination, including Guillain-Barré syndrome (GBS) and thrombosis with thrombocytopenia syndrome (TTS) after Janssen COVID-19 vaccination and myocarditis after mRNA (Pfizer-BioNTech and Moderna) COVID-19 vaccination. On July 22, 2021, the Advisory Committee on Immunization Practices reviewed updated benefit-risk analyses after Janssen and mRNA COVID-19 vaccination and concluded that the benefits outweigh the risks for rare serious adverse events after COVID-19 vaccination. Continued COVID-19 vaccination will prevent COVID-19 morbidity and mortality far exceeding GBS, TTS, and myocarditis cases expected. Information about rare adverse events should be disseminated to providers, vaccine recipients, and the public.

Grouping Race and Ethnicity to Monitor COVID-19 Outcomes and Vaccination Coverage: CDC released an *MMWR* on <u>alternative methods for grouping race and ethnicity to monitor COVID-19 outcomes and vaccination coverage</u>. Analyses of race and ethnicity in COVID-19 data to identify and monitor disparities are complicated by missing or unknown data. Methods that use more race information when ethnicity information is missing resulted in higher estimated COVID-19 case counts, incidence, and vaccination coverage for most racial groups studied; however, these methods have limitations and warrant further examination of potential bias. Ongoing work with experts is needed to identify methods for optimizing race and ethnicity data when data are incomplete. Multiple data sources are needed to monitor disparities and continued efforts are needed to strengthen the reporting of these data, consistent with CDC's

Data Modernization Initiative.

Effectiveness of COVID-19 Vaccines in Preventing Hospitalization: CDC released an *MMWR* on the <u>effectiveness of the COVD-19 vaccine in preventing hospitalizations among adults aged ≥65</u> years. This report was released as an *MMWR* Early Release on August 6. Clinical trials of COVID-19 vaccines currently authorized for emergency use in the United States (Pfizer-BioNTech, Moderna, and Janssen [Johnson & Johnson]) have shown high efficacy in preventing symptomatic (including moderate to severe) COVID-19. Among adults aged 65–74 years, effectiveness of full vaccination for preventing hospitalization was 96% for Pfizer-BioNTech, 96% for Moderna, and 84% for Janssen COVID-19 vaccines; among adults aged ≥75 years, effectiveness of full vaccination for preventing hospitalization was 91% for Pfizer-BioNTech, 96% for Moderna, and 85% for Janssen COVID-19 vaccines. Efforts to increase vaccination coverage are critical to reducing the risk for COVID-19–related hospitalization, particularly in older adults.

Rapid Increase in Circulation of the Delta Variant: CDC released an *MMWR* on the <u>rapid</u> increase in circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant. This report was released as an *MMWR* Early Release on August 6. The highly transmissible B.1.617.2 (Delta) variant of SARS-CoV-2 has become the predominant circulating U.S. strain. During April–June 2021, COVID-19 cases caused by the Delta variant increased rapidly in Mesa County, Colorado. Compared with that in other Colorado counties, incidence, intensive care unit admissions, COVID-19 case fatality ratios, and the proportion of cases in fully vaccinated persons were significantly higher in Mesa County. Crude vaccine effectiveness against symptomatic infection was estimated to be 78% for Mesa County and 89% for other Colorado counties. Vaccination is critical for preventing infection, serious illness, and death associated with SARS-CoV-2 infection (including the Delta variant). Multicomponent prevention strategies, such as masking in indoor settings irrespective of vaccination status as well as optimal surveillance testing and infection prevention and control, should be considered in areas of high incidence.

Reduced Risk of Reinfection After COVID-19 Vaccination: CDC released an *MMWR* on <u>the</u> <u>reduced risk of reinfection with SARS-CoV-2 after COVID-19 vaccination</u>. This report was released as an *MMWR* Early Release on August 6. Reinfection with human coronaviruses, including SARS-CoV-2, the virus that causes COVID-19, has been documented. Currently, limited evidence concerning the protection afforded by vaccination against reinfection with SARS-CoV-2 is available. Among Kentucky residents infected with SARS-CoV-2 in 2020, vaccination status of those reinfected during May–June 2021 was compared with that of residents who were not reinfected. In this case-control study, being unvaccinated was associated with 2.34 times the odds of reinfection compared with being fully vaccinated. To reduce their likelihood for future infection, all eligible persons should be offered a COVID-19 vaccine, even those with previous SARS-CoV-2 infection. The CDC Newsroom issued a media statement on the study.

Other Resources

Social Media Toolkit: <u>Find social media ready COVID-19 content</u> on a variety of topics to help you successfully communicate with your audiences. View social media content on the COVID-19 variants.

Communication Toolkit: CDC created this <u>communication toolkit</u> to help public health professionals, health departments, community organizations, and healthcare systems and providers reach populations who may need COVID-19 prevention messaging in their native languages.

Unproven COVID-10 Claims: As part of the FDA's effort to protect consumers, on August 10, FDA issued a warning letter to <u>Secret of the Islands</u> for selling unapproved products with unproven COVID-19 claims. Consumers concerned about COVID-19 should consult with their health care provider.

Back to School Resources: A Back to School toolkit (<u>English</u> and <u>Spanish</u>) for school district leaders, teachers, parent leaders, and school supporters that want to help increase confidence in and uptake of COVID-19 vaccines in their school. Toolkit includes vaccination clinic guides, resources for parent leader meetings, and more. Visit <u>our resource hub</u> with materials on how to reach for students, teens, parents, and young adults as health professionals, organizations, and community leaders.

Families and COVID-19: CDC <u>released information for parents and caregivers on how to protect</u> <u>their families from COVID-19</u>. Not everyone is able to get vaccinated, so you may be confused about how to keep your family safe, especially if your family has vaccinated and unvaccinated members. This guidance provides things to think about and ways to help family members cope.

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