September 7, 2021

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

We invite you to a special **Tribal Telehealth Information Listening Session on September 9**th **from 2:00 – 3:00 PM ET**. Subject matter experts from across the Department of Health and Human Services (HHS), including the Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Medicare and Medicaid Services (CMS), and the Indian Health Service (IHS) will provide an overview of their broadband activities and share resources for Tribes. They will also be joined by presenters from the Federal Communications Commission (FCC), United States Department of Agriculture (USDA), and the Department of Commerce (DOC). The agenda is below and you can register for the event here.

HHS Tribal Consultation Updates

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 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 ELCKC website. To register, click here.

Departmental Updates

Symposium on Missing and Murdered Indigenous Peoples: HHS along with the Departments of Justice and Interior is 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 (IHS) Update: The IHS continues to focus on administering as many COVID-19 vaccines as possible with more than 1.5 million vaccine doses to patients, employees, and tribal and urban community members. Over 59 percent of American Indian and Alaska Native adult patients have received at least one vaccine dose, and approximately 49 percent have been fully vaccinated. IHS is implementing the 3rd dose for moderately to severely immune-compromised individuals. IHS facilities are reaching out and utilizing electronic tools to identify patients who are recommended to get this 3rd vaccine dose.

The IHS invites you to the following events:

- September 8-9: <u>The IHS Information Systems Advisory Committee Fall Semi-Annual</u>
 <u>Meeting (Virtual)</u>
- September 9 from 3:00 PM 4:00 PM (ET): <u>IHS September Update Call to Tribal Leaders</u>
 and Urban Indian Organization Leaders (Virtual)
- September 14: <u>IHS Tribal Leaders Diabetes Committee Meeting (Virtual)</u>
- September 14-16: 2021 Virtual Annual Tribal Self-Governance Conference

Centers for Medicare and Medicaid Services (CMS) Update: On August 30th, CMS issued guidance that provides essential information to states as they navigate the options available to advance COVID-19 vaccination and testing, and the Medicaid program's broader aim of providing much-needed health coverage for millions of eligible individuals. For more information, see the press release here.

This guidance explains that under the American Rescue Plan (ARP), states can receive a temporary increase in the Federal Medical Assistance Percentage (FMAP) if they newly extend Medicaid coverage to certain low-income adults. Additionally, the ARP temporarily makes 100% federal matching funds available for states' Medicaid and CHIP expenditures for COVID-19 vaccine administration. Also, state expenditures for Medicaid services received through Urban Indian Organizations and certain Native Hawaiian health care entities will receive a temporary match at 100% FMAP. To view the FMAP State Health Official letter, please visit: https://www.medicaid.gov/federal-policy-guidance/downloads/sho-21-004.pdf - PDF

On August 27th, CMS Announced \$80 million in grant awards to 60 Navigator organizations: The Great Plains Tribal Chairmen's Health Board received a grant to help support American Indian and Alaska Native enrollment. See the press release and list of other recipients here: https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open

COVID-19 FAQ update: CMS has updated the COVID-19 FAQs on Medicare fee-for-service (FFS) billing for Indian Health Service (IHS) hospitals on pages 179 – 180 for IHS and critical access hospitals (CAH), see new question 6 listed in <u>Section QQ</u>. Refer to <u>Hospital Billing for Remote Services, Section LL</u> for additional information. **Note:** Currently there is no waiver in place for timely filing.

Health Resources and Services Administration (HRSA) Update: On August 31st, CDC issued a Dear Tribal Leader Letter (attached) announcing the establishment of an Office of Intergovernmental and External Affairs, where an office of Tribal Affairs will be maintained. This transition elevates the critical role of tribal affairs within HRSA, and leverages HRSA's regional infrastructure, staff, and external engagement to meet unique tribal health needs.

Vaccine Updates

FDA Approves First COVID-19 Vaccine: On August 23, the FDA <u>approved the first COVID-19</u> <u>vaccine</u>. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

Booster Shot: CDC <u>released a page on booster shots for COVID-19</u>. This page includes information on when you can get the booster, who will get the booster first, and more.

Possibility of COVID-19 Illness After Vaccination: CDC updated the page on the possibility of COVID-19 illness after vaccination. COVID-19 vaccines protect people against severe illness, including disease caused by Delta and other variants circulating in the U.S. COVID-19 vaccines protect people from getting infected and severely ill, and significantly reduce the likelihood of hospitalization and death.

Myocarditis Outcomes Investigation: CDC is actively investigating reports of people developing myocarditis (inflammation of the heart muscle) after receiving a mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna). Most of these people fully recover, but information is not yet available about potential long-term effects. Therefore, CDC is conducting surveys of patients (or their parents or guardians) and healthcare providers to gather information about myocarditis after mRNA COVID-19 vaccination.

Advisory Committee Meeting on Pfizer's Application for Booster: The FDA <u>announced a virtual meeting of its Vaccines and Related Biological Products Advisory Committee</u> to discuss the matter of additional doses of COVID-19 vaccines, and specifically to discuss the Pfizer-BioNTech supplemental Biologics License Application for administration of a third ("booster") dose of Comirnaty (COVID-19 Vaccine, mRNA) in individuals 16 years of age and older. The meeting will be held on Sept. 17, 2021, from 8:30 a.m. to 3:45 p.m. EST.

COVID-19 Vaccinations: CDC <u>updated the page on COVID-19 vaccinations</u>. View <u>how CDC is</u> making vaccine recommendations. These updates include:

- New Advisory Committee on Immunization Practices (ACIP) recommendation for use of the U.S. Food and Drug Administration (FDA)-approved Pfizer-BioNTech (COMIRNATY) COVID-19 Vaccine in persons aged ≥16 years
- Updated information in Key points to reflect currently available evidence
- Updated information on COVID-19 vaccines in the <u>Background section</u>
- Updated information in the section on Considerations for use of an additional dose of COVID-19 vaccine following a primary vaccine series
- Updated laboratory testing information on timing of immune-based tests for tuberculosis infection in relation to COVID-19 vaccine administration

Vaccination Demographic Data: CDC updated the page on reporting COVID-19 vaccination demographic data. On August 31, 2021, CDC updated its algorithm for assigning a race/ethnicity category for vaccine recipients to align with U.S. Census Bureau race/ethnicity classifications, and beginning August 9, 2021, submitting entities will have the ability to update or delete previously submitted records using new functionality available in CDC's Data Clearinghouse.

Pfizer-BioNTech Shelf-Life Extension: On Aug. 22, the FDA <u>updated the Pfizer-BioNTech</u> <u>Emergency Use Authorization (EUA)</u> to support the extension of shelf-life of the Pfizer-BioNTech COVID-19 Vaccine stored at -90 degrees to -60 degrees Celsius from 6 months to 9 months. The <u>extension</u> is also applicable to batches that might have expired prior to the EUA amendment, provided the product was stored at the same temperatures.

Vaccine Adverse Event Reporting System: CDC <u>updated their information on the Vaccine</u>

<u>Adverse Event Reporting System (VAERS)</u> – an early warning system used to monitor adverse events that happen after vaccination – to include a <u>video on VAERS and vaccine safety</u>

Testing, Tracing, and Treatment

Testing in Schools: CDC <u>released information on testing in schools</u>. As schools go back to inperson learning, some may offer regular COVID-19 testing for students and staff. This means testing is offered regularly, even for people who don't have symptoms of COVID-19. Many schools will also offer testing for people with symptoms of COVID-19 or who have been exposed to someone with COVID-19. <u>View sample letters</u> school districts can use to share information about school COVID-19 testing programs and <u>frequently asked questions</u> for parents and staff about these school testing programs. Find <u>communication toolkits</u> and <u>sample social media graphics</u> on the school testing program.

Therapeutic Management of Hospitalized Adults with COVID-19: NIH <u>updated the therapeutic</u> <u>management for hospitalized adults</u> with COVID-19. This update includes an added section on dosing regimens and comments on current therapeutics available.

Therapeutics Update: On August 27, the FDA made changes to the authorized use of the monoclonal antibodies bamlanivimab and etesevimab, administered together. The Emergency Use Authorization (EUA) now authorizes the use of bamlanivimab and etesevimab, administered together, only in states, territories, and U.S. jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%. FDA has posted a <u>list of states, territories, and U.S. jurisdictions</u> in which bamlanivimab and etesevimab administered together are currently authorized, and a list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab administered together, are not currently authorized, and will periodically update both lists as new data and information becomes available.

Misuse of Invermectin to Prevent or Treat COVID-19: On August 30, FDA issued a letter to veterinarians and retailers asking for assistance in sharing important safety information with consumers about the dangerous misuse of animal ivermectin to prevent or treat COVID-19 in people. As noted in many recent news stories and in a Health Alert from the CDC, poison control centers across the U.S. are seeing a sharp spike in reports of people suffering adverse health effects after taking animal ivermectin. People are purchasing various highly concentrated animal ivermectin drug formulations such as "pour-on," injectable, paste, and "drench" that are intended for horses, cattle, and sheep, and taking these drugs has made some people very sick. Even if animal drugs have the same active ingredient as an approved human drug, animal drugs have not been evaluated for safety or effectiveness in humans. Treating human medical conditions with veterinary drugs can be very dangerous.

Testing Communication Toolkit: CDC <u>released a testing communication toolkit</u>. This toolkit provides communication resources on COVID-19 testing, including factsheets and social media. You can use these resources to communicate about testing in your community.

Funding

Mental Health Funding: With the COVID-19 pandemic taking a toll on many young people, the Substance Abuse and Mental Health Services Administration (SAMHSA) is awarding grants that will strengthen the structures that serve the mental health needs of our nation's youth. The first raises awareness of mental health issues for youths and trains school personnel. The second coordinates treatment for young people who have emotional disorders. The first-year awards for the two programs total \$74.2 million. Furthermore, HHS awarded \$10.7 million from the American Rescue Plan (ARP) to expand pediatric mental health care access by integrating telehealth services into pediatric care. The awards were made through the Health Resources and Services Administration (HRSA).

Research

COVID-19 Vaccination Coverage: CDC released an *MMWR*, which was an early release from August 27, on <u>COVID-19 vaccination coverage among adolescents aged 12-17 years</u>. Although

more common among adults, severe COVID-19 illness and hospitalization occur among adolescents. As of July 31, 2021, coverage with ≥1 dose of COVID-19 vaccine among adolescents aged 12–17 years was 42%, and 32% had completed the series. Series completion rates varied widely by state, ranging from 11% to 60%, and was 25% for adolescents aged 12–13 years, 30% for those aged 14–15 years, and 40% for those aged 16–17 years. Improving adolescent COVID-19 vaccination coverage is crucial to reduce COVID-19—associated morbidity and mortality among adolescents and can help facilitate safer reopening of schools for in-person learning.

COVID-19 Infections and Hospitalizations: CDC released an *MMWR* on <u>SARS-COV-2 infections</u> and hospitalizations among persons aged 16 years and older by vaccination status. This report was released as an *MMWR* Early Release on August 24. Although COVID-19 vaccines are highly effective, some fully vaccinated persons will be infected with SARS-CoV-2. During May 1–July 25, 2021, among 43,127 SARS-CoV-2 infections in residents of Los Angeles County, California, 10,895 (25.3%) were in fully vaccinated persons, 1,431 (3.3%) were in partially vaccinated persons, and 30,801 (71.4%) were in unvaccinated persons. On July 25, infection and hospitalization rates among unvaccinated persons were 4.9 and 29.2 times, respectively, those in fully vaccinated persons. In July, when the Delta variant was predominant, cycle threshold values were similar for unvaccinated, partially vaccinated, and vaccinated persons. Efforts to enhance COVID-19 vaccination coverage, in coordination with other prevention strategies, are critical to preventing COVID-19—related hospitalizations and deaths.

Effectiveness of COVID-19 Vaccines in Preventing Infections: CDC released an MMWR on the effectiveness of COVID-19 vaccines in preventing SARS-CoV-2 infection among frontline workers before and during the Delta variant predominance. This report was released as an MMWR Early Release on August 24. During December 14, 2020—April 10, 2021, data from the HEROES-RECOVER Cohorts, a network of prospective cohorts among frontline workers, showed that the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines were approximately 90% effective in preventing symptomatic and asymptomatic infection with SARS-CoV-2 in real-world conditions. This report updates vaccine effectiveness (VE) estimates including all COVID-19 vaccines available through August 14, 2021, and examines whether VE differs for adults with increasing time since completion of all recommended vaccine doses. VE before and during SARS-CoV-2 B.1.617.2 (Delta) variant predominance, which coincided with an increase in reported COVID-19 vaccine breakthrough infections, were compared. Although these interim findings suggest a moderate reduction in the effectiveness of COVID-19 vaccines in preventing infection, the sustained two thirds reduction in infection risk underscores the continued importance and benefits of COVID-19 vaccination.

Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations: CDC released an *MMWR* on the <u>sustained effectiveness of Pfizer-BioNTech</u>
<u>and Moderna vaccines against COIVD-19 associated hospitalizations</u> among adults. This report
was released as an *MMWR* Early Release on August 18. COVID-19 mRNA vaccines provide
strong protection against severe COVID-19; however, the duration of protection is uncertain.
Among 1,129 patients who received 2 doses of a mRNA vaccine, no decline in vaccine
effectiveness against COVID-19 hospitalization was observed over 24 weeks. Vaccine

effectiveness was 86% 2–12 weeks after vaccination and 84% at 13–24 weeks. Vaccine effectiveness was sustained among groups at risk for severe COVID-19. mRNA vaccine effectiveness against COVID-19—associated hospitalizations was sustained over 24 weeks; ongoing monitoring is needed as new SARS-CoV-2 variants emerge. To reduce hospitalization, all eligible persons should be offered COVID-19 vaccination.

New COVID-19 Cases and Hospitalizations Among Adults by Vaccination Status: CDC released an MMWR on new COVID-19 cases and hospitalizations among adults by vaccination status. This report was released as an MMWR Early Release on August 18. Real-world studies of population-level vaccine effectiveness against laboratory-confirmed SARS-CoV-2 infection and COVID-19 hospitalizations are limited in the United States. During May 3–July 25, 2021, the overall age-adjusted vaccine effectiveness against hospitalization in New York was relatively stable (91.9%–95.3%). The overall age-adjusted vaccine effectiveness against infection for all New York adults declined from 91.7% to 79.8%. These findings support the implementation of a multicomponent approach to controlling the pandemic, centered on vaccination, as well as other prevention strategies such as masking and physical distancing.

Vouching for Vaccine Safety: NIH released information on new research examining vaccine hesitancy. The article highlights how the data safety and monitoring board's (DSMB) recommendations helped shift the recruitment focus of vaccine administration. In the end, the percentage of Hispanic participants exceeded Hispanic communities as a share of the U.S. population. Although final percentages for African American, Asian, American Indian and Alaska Native, and Native Hawaiian and Other Pacific Islander communities were lower than in the general population, the studies addressed initial imbalances and ultimately achieved greater racial diversity than many previous studies. Many people still have doubts regarding the COVID-19 vaccine, and this study highlights the need to answer questions and give patients information to erase misconceptions and allow their patients to make a thoughtful decision about the vaccine.

The Impact of the COVID-19 Pandemic on Major HHS Data Systems: The COVID-19 pandemic and policy responses, including stay-at-home orders and expanded use of telework, disrupted data collection for major HHS data systems. This brief identifies the impact of the pandemic on 29 HHS statistical surveys and administrative data systems widely used by policymakers and the public. Changes in methodology to accommodate the pandemic and the addition of new content related to COVID-19 were identified through a review of information on data system websites and informal interviews with data system leads. Recommendations for data users are provided to adapt to pandemic-related changes in available data, including the use of alternative data sources, new types of data collection, and methodological approaches to adjust data.

Other Resources

COVID-19 Vaccines for Moderately to Severely Immunocompromised People: CDC <u>updated</u> their page on COVID-19 vaccines for moderately to severely immunocompromised people. This

update includes an added section regarding vaccine cards and the additional dose. At your first vaccination appointment, you should have received a vaccination card that tells you what COVID-19 vaccine you received, the date you received it, and where you received it. Bring this vaccination card to your additional dose vaccination appointment.

Back to School During COVID-19: Substance Abuse and Mental Health Services Administration (SAMHSA) <u>released information on going back to school during COVID-19</u>. These resources are designed to address mental health and resiliency in school settings.

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 TribalAffairs@hhs.gov