January 28, 2022

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

The White House Council on Native American Affairs (WHCNAA) is hosting a Tribal Leader engagement session on Monday, January 31 from 1:00 PM-3:30 PM ET. The first half of the session will focus on the Economic Development, Energy, and Infrastructure Committee of the WHCNAA and explore the implementation of the Bipartisan Infrastructure Law (BIL). Secretary Becerra will join other cabinet leaders for the second half of the session, focusing on the Public Safety and Justice Committee of the WHCNAA and its implementation of the Executive Order on Improving Public Safety and Criminal Justice for Native Americans and Addressing the Crisis of Missing and Murdered Indigenous People (November 15, 2021). Tribal Leaders are invited to share their recommendations and comments during the session. You can register for the event here.

HHS Tribal Consultation Updates

Food and Drug Administration (FDA): The U.S. Food and Drug Administration (FDA) is initiating tribal consultation on the recently published proposed rule "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water." The proposed rule <u>published</u> in the Federal Register on December 6, 2021. FDA Deputy Commissioner for Food Policy and Response Frank Yiannas invites you or your designated consultation official to a consultation conference call on February 4, 2022 at 1:00 PM ET.

PLEASE NOTE THE CONFERENCE CALL INFORMATION HAS CHANGED. The call will now take place via Zoom.gov. To participate in the call, you <u>must register here</u>. FDA sincerely apologizes for the inconvenience. For additional information, including FDA's Dear Tribal Leader Letter Invitation to Consultation, please visit FDA's website here. Please reach out to FDA's Intergovernmental Affairs staff at IGA@fda.hhs.gov if you have any questions.

Centers for Disease Control and Prevention (CDC): The National Institute for Occupational Safety and Health (NIOSH) within CDC is hosting a tribal consultation session on a draft document entitled, "American Indian and Alaska Native (Al/AN) Worker Safety and Health Strategic Plan, 2022-2031." The consultation is on February 3, 2022, from 4:15 to 6:00 PM ET. Registration is required. For more information, including a copy of the draft strategic plan, and to register, visit www.cdc.gov/tribal/consultation-support/tribal-consultation/index.html.

Centers for Medicare and Medicaid Services (CMS): On February 10th from 2:00 – 3:00 PM ET, the CMS, Division of Tribal Affairs, in collaboration with the CMS Center for Clinical Standards and Quality (CCSQ), will hold an All Tribes Consultation call on how your health facilities can utilize the CMS Quality, Certification and Oversight Reports (QCOR) website to search for CMS certification numbers (CCN) of facilities subject to the IFC. You can register here. CMS will also answer tribal concerns and questions raised during the previous webinar held on November 18, 2021. All new questions for the upcoming webinar must be emailed in advance to the CMS

<u>Division of Tribal Affairs</u> by close of business on February 2, 2022. Please see additional information related to the IFC below:

- View a list of frequently asked questions updated as of January 20, 2022
- View a decision tree to determine if the rule applies to your facility
- View the December 28 guidance (QSO-22-07-ALL)
- View the January 14 guidance
- View the interim final rule

Departmental Updates

Indian Health Service (IHS): On January 14th, IHS issued a Dear Tribal Leader Letter announcing the publication of the final rule supplementing acquisition regulations, specifically procedures for contracting, under the Buy Indian Act of 1910 (Buy Indian Act) at 25 U.S.C. § 47, which provides the Indian Health Service (IHS or Agency) with authority to set-aside procurement contracts for Indian-owned and controlled businesses. The final rule supplements the Federal Acquisition Regulations and the Department of Health and Human Services Acquisition Regulations (48 C.F.R. Parts 326 and 352) to ensure that preference is given to Indian labor and industry when determining set-asides for IHS solicitations under the authority of the Buy Indian Act.

Centers for Disease Control and Prevention (CDC): The CDC All-State, Tribal, Local, and Territorial (STLT) Update Call will be on Monday, January 31st, 2:00–2:45 PM ET. CDC hosts a weekly national call series to provide state, tribal, local, and territorial partners with the latest information on the COVID-19 outbreak and U.S. preparedness efforts. For more information, email eocevent424@cdc.gov.

Administration for Native Americans (ANA): The ANA partnered with IHS and CDC to develop a Domestic Violence Awareness Public Service Announcement campaign. In accordance with President Biden's Executive Order on Improving Public Safety and Criminal Justice for Native Americans and Addressing the Crisis of Missing or Murdered Indigenous People (MMIP), "Native Americans face unacceptably high levels of violence, and are victims of violent crime at a rate much higher than the national average." Native American women are disproportionately the victims of sexual and gender-based violence, including intimate partner homicide, and approximately half of Native American women have experienced physical violence by an intimate partner. Each PSA is geared toward a specific topic or focus.

- Warning Signs and Prevention Skills
- Seeking Services for Survivors (Youth Focused)
- Seeking Services for Survivors (Male Focused)
- Seeking Services for Survivors (Female Focused)
- Supporting Survivors and Responding to Domestic Violence
- Increasing Community Safety

<u>Funding</u>

CMS Commits Over \$49 Million to Reduce Uninsured Rate Among Children and Boost Medicaid Enrollment Among Parents, Pregnant People: The Centers for Medicare & Medicaid Services (CMS) committed a record \$49.4 million to fund organizations that can connect more eligible children, parents, and pregnant individuals to health care coverage through Medicaid and the Children's Health Insurance Program (CHIP). Awardees—including state/local governments, tribal organizations, federal health safety net organizations, non-profits, schools, and others—will receive up to \$1.5 million each for a three-year period to reduce the number of uninsured children by advancing Medicaid/CHIP enrollment and retention. Applications will be accepted through March 28, 2022. For more information, visit https://www.grants.gov/web/grants/view-opportunity.html?oppId=337485

HHS Distributing \$2 Billion More in Provider Relief Fund Payments to Health Care Providers Impacted by the COVID-19 Pandemic: The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), is making more than \$2 billion in Provider Relief Fund (PRF) Phase 4 General Distribution payments to more than 7,600 providers across the country this week. These payments come on the heels of the nearly \$9 billion in funding that was already released by HHS in December 2021. With today's announcement, a total of nearly \$11 billion in PRF Phase 4 payments has now been distributed to more than 74,000 providers in all 50 states, Washington D.C., and five territories. This is in addition to HRSA's distribution of American Rescue Plan (ARP) Rural payments totaling nearly \$7.5 billion in funding to more than 43,000 providers in December 2021.

Biden-Harris Administration Awards \$103 Million in American Rescue Plan Funds to Reduce Burnout and Promote Mental Health and Wellness Among Health Care Workforce: The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced \$103 million in awards to improve the retention of health care workers and help respond to the nation's critical staffing needs — exacerbated by the COVID-19 pandemic — by reducing burnout and promoting mental health and wellness among the health care workforce. These awards will fund evidence-informed programs, practices and training, with a specific focus on providers in underserved and rural communities. The funds, secured through the Biden-Harris Administration's American Rescue Plan, will be disbursed to 45 grantees.

Vaccines

Janssen COVID-19 Vaccine: The FDA announced revisions to the Janssen COVID-19 Vaccine Fact Sheet for Heath Care Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers. These revisions are in response to new safety information regarding the serious risk of Immune Thrombocytopenia (ITP), a disorder that can cause easy or excessive bruising and bleeding due to very low levels of platelets, following administration of the Janssen COVID-19 Vaccine. Specifically, the Fact Sheet for Health Care Providers includes

information about reports of adverse events following use of the vaccine which suggest an increased risk of ITP during the 42 days following vaccination, and that individuals with a history of ITP should discuss the risk and the potential need for platelet monitoring following vaccination with their healthcare provider. The Fact Sheet for Recipients and Caregivers includes additional information under the questions, "What should you mention to your vaccination provider before you get the Janssen COVID-19 Vaccine?" and "What are the risks of the Janssen COVID-19 Vaccine?" regarding ITP, as well as what to look for and when to seek medical attention. The FDA and CDC continue to monitor the level of potential excess risk. Individuals should speak to their health care provider to determine which COVID-19 vaccine is most appropriate for their own situation.

Testing, Tracing, and Treatment

Free At-Home Testing: Every home in the U.S. is eligible to order four free at-home COVID-19 tests. The tests are completely free. <u>Order here.</u> Orders will usually ship in 7-12 days. Order your tests now so you have them when you need them. If you need a COVID-19 test now, please see <u>other testing resources</u> for free testing locations in your area.

Operation Expanded Testing (OpET): Operation Expanded Testing (OpET) provides no-cost laboratory-based testing to childcare centers, K-12 schools, congregate settings, and other communities who have been disproportionately affected by the COVID-19 pandemic. For more information, see Operation Expanded Testing | CDC or contact OpET at eocevent589@cdc.gov.

Interim Guidance for Antigen Testing for SARS-CoV-2: CDC <u>updated its interim guidance for antigen testing for SARS-CoV-2</u>. This interim guidance is intended for healthcare providers who order antigen tests, receive antigen test results, or perform point-of-care testing, as well as for laboratory professionals who perform antigen testing in a laboratory setting or at the point-of-care and report those results.

Contact Tracing for COVID-19: CDC <u>updated their information on contact tracing for COVID-19</u>. Specifically, CDC updated guidelines for isolation and quarantine for the public. These recommendations do not apply to healthcare personnel and do not supersede state, local, tribal or territorial laws, rules, and regulations.

FDA Updated the COVID-19 Test Frequently Asked Questions: On January 22, the FDA <u>added</u> <u>to the COVID-19 Test Frequently Asked Questions (FAQs)</u> to include the question, 'Can I use an authorized at-home COVID-19 diagnostic test if it was left outside in freezing temperatures?'.

FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant: In light of the most recent information and data available, the FDA revised the authorizations for two monoclonal antibody treatments – bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) – to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is

susceptible to these treatments. Because data show these treatments are highly unlikely to be active against the omicron variant, which is circulating at a very high frequency throughout the United States, these treatments are not authorized for use in any U.S. states, territories, and jurisdictions at this time. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of these treatments may be authorized in these regions.

FDA Takes Actions to Expand Use of Treatment for Outpatients with Mild-to-Moderate COVID-19: Recently, the U.S. Food and Drug Administration took two actions to expand the use of the antiviral drug Veklury (remdesivir) to certain non-hospitalized adults and pediatric patients for the treatment of mild-to-moderate COVID-19 disease. This provides another treatment option to reduce the risk of hospitalization in high-risk patients. Previously, the use of Veklury was limited to patients requiring hospitalization.

Antibody Testing Guidelines: CDC <u>updated its interim guidelines for COVID-19 antibody testing</u> in clinical and public health settings. Specifically, the guidelines include added language for people that are up to date with their vaccines and quarantine and isolation recommendations.

Research

Effectiveness of a Third Dose of Pfizer-BioNTech and Moderna Vaccines in Preventing COVID-19 Hospitalizations: CDC released an MMWR on the effectiveness of a third dose of Pfizer-BioNTech and Moderna vaccines in preventing COVID-19 hospitalizations among immunocompetent and immunocompromised adults in the United States from August − December 2021. For adults aged ≥18 years who received 2 doses of an mRNA COVID-19 vaccine, third doses are recommended. However, the associated benefits in preventing COVID-19 hospitalization are incompletely understood. In a study of hospitalized adults, compared with receipt of 2 mRNA COVID-19 vaccine doses, receipt of a third dose increased vaccine effectiveness against hospitalization among adults without and with immunocompromising conditions, from 82% to 97% and from 69% to 88%, respectively. Administration of a third COVID-19 mRNA vaccine dose as part of a primary series among immunocompromised adults, or as a booster dose among immunocompetent adults, provides improved protection against COVID-19—associated hospitalization.

COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis: CDC released an MMWR on COVID-19 cases and hospitalizations by COVID-19 vaccination status and previous COVID-19 diagnosis in California and New York from May – November 2021. Data are limited regarding the risks for SARS-CoV-2 infection and hospitalization after COVID-19 vaccination and previous infection. During May—November 2021, case and hospitalization rates were highest among persons who were unvaccinated without a previous diagnosis. Before Delta became the predominant variant in June, case rates were higher among persons who survived a previous infection than persons who were vaccinated alone. By early October, persons who survived a previous infection had lower case rates than persons who were vaccinated alone. Although the epidemiology of COVID-19 might change as

new variants emerge, vaccination remains the safest strategy for averting future SARS-CoV-2 infections, hospitalizations, long-term sequelae, and death. Primary vaccination, additional doses, and booster doses are recommended for all eligible persons. Additional future recommendations for vaccine doses might be warranted as the virus and immunity levels change.

Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS-CoV-2 High Transmission Periods: CDC released an MMWR on trends in disease severity and health care utilization during the early Omicron variant period compared with previous SARS-CoV-2 high transmission periods in the United States from December 2020 – January 2022. This MMWR was posted as an Early Release on January 25. The SARS-CoV-2 B.1.1.529 (Omicron) variant became predominant in the United States by late December 2021, leading to a surge in COVID-19 cases and associated ED visits and hospitalizations. Despite Omicron seeing the highest reported numbers of COVID-19 cases and hospitalizations during the pandemic, disease severity indicators, including length of stay, ICU admission, and death, were lower than during previous pandemic peaks. Although disease severity appears lower with the Omicron variant, the high volume of hospitalizations can strain local health care systems and the average daily number of deaths remains substantial. This underscores the importance of national emergency preparedness, specifically, hospital surge capacity and the ability to adequately staff local health care systems. In addition, being up to date on vaccinations and following other recommended prevention strategies are critical to preventing infections, severe illness, or death from COVID-19.

COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults: CDC released an MMWR on COVID-19 incidence and death rates among unvaccinated and fully vaccinated adults with and without booster doses during periods of Delta and Omicron variant emergence in 25 jurisdictions from April 4 − December 25, 2021. This MMWR was posted as an Early Release on January 21. Although COVID-19 vaccine effectiveness decreased with emergence of the Delta variant and waning of vaccine-induced immunity, protection against hospitalization and death has remained high. In 25 U.S. jurisdictions, decreases in case incidence rate ratios for unvaccinated versus fully vaccinated persons with and without booster vaccine doses were observed when the Omicron variant emerged in December 2021. Protection against infection and death during the Delta-predominant period and against infection during Omicron emergence were higher among booster vaccine dose recipients, especially among persons aged 50−64 and ≥65 years. COVID-19 vaccination protected against SARS-CoV-2 infection, even as the Omicron variant became predominant. All eligible persons should stay up to date with COVID-19 vaccination.

Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19-Associated Emergency

Department and Urgent Care Encounters and Hospitalizations: CDC released an MMWR on the effectiveness of a third dose of mRNA vaccines against COVID-19-associated emergency department and urgent care encounters and hospitalizations among adults during periods of Delta and Omicron variant predominance in ten states between August 21 – January 2022. This MMWR was posted as an Early Release on January 21. COVID-19 mRNA vaccine effectiveness

(VE) in preventing COVID-19 might decline because of waning of vaccine-induced immunity or variant immune evasion. VE was significantly higher among patients who received their second mRNA COVID-19 vaccine dose <180 days before medical encounters compared with those vaccinated ≥180 days earlier. During both Delta- and Omicron-predominant periods, receipt of a third vaccine dose was highly effective at preventing COVID-19—associated emergency department and urgent care encounters (94% and 82%, respectively) and preventing COVID-19—associated hospitalizations (94% and 90%, respectively). All unvaccinated persons should start vaccination as soon as possible. All adults who have received mRNA vaccines during their primary COVID-19 vaccination series should receive a third dose when eligible, and eligible persons should stay up to date with COVID-19 vaccinations.

Mix-and-Match Trial Finds Additional Dose of COVID-19 Vaccine Safe: NIH released an article on NIAID-sponsored study that assessed mix-and-match COVID-19 booster vaccinations. All combinations of primary and booster vaccine resulted in increased neutralizing antibody levels (ranging from 4.2- to 76-fold higher levels than those detected prior to boost.) Likewise, all primary-boost combinations increased binding antibody levels 4.6- to 56-fold. No serious vaccine-related adverse events were reported. The trial is ongoing and continuing to enroll participants. Scientists concluded, "these data strongly suggest that homologous and heterologous booster vaccination will increase protective efficacy against symptomatic SARS-CoV-2 infection."

Social Connectedness, Sleep, and Physical Activity Associated with Better Mental Health Among Youth During the COVID-19 Pandemic: The NIH released information on an NIH-supported study on how social connectedness, sleep, and physical activity are associated with better mental health among youth during the COVID-19 pandemic. The study found that supportive relationships with family and friends and healthy behaviors, like engaging in physical activity and better sleep, appeared to shield against the harmful effects of the pandemic on adolescents' mental health. The research, published today in the *Journal of Adolescent Health*, was supported by the National Institute on Drug Abuse (NIDA) and other entities at the National Institutes of Health. The research is based on data from the Adolescent Brain Cognitive Development (ABCD) Study, the largest long-term study of brain development and child health ever conducted in the United States.

Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19: CDC released an MMWR on racial and ethnic disparities in receipt of medications for treatment of COVID-19 in the United States, from March 2020 – August 2021. This report was posted online as an MMWR Early Release on January 14. Racial and ethnic disparities in SARS-CoV-2 infection risk and death from COVID-19 have been well documented. Analysis of data from 41 health care systems participating in the PCORnet, the National Patient-Centered Clinical Research Network found lower use of monoclonal antibody treatment among Black, Asian, and Other race and Hispanic patients with positive SARS-CoV-2 test results, relative to White and non-Hispanic patients. Racial and ethnic differences were smaller for inpatient administration of remdesivir and dexamethasone. Equitable receipt of COVID-19 treatments by race and ethnicity

along with vaccines and other prevention practices are essential to reduce inequities in severe COVID-19—associated illness and death.

Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18: CDC released an *MMWR* on <u>risk for newly diagnosed diabetes >30 days after SARS-CoV-2 infection among persons aged <18 in the United States from March 1, 2020 – June 28, 2021. This report was posted online as an *MMWR* Early Release on January 7. SARS-CoV-2 infection is associated with worsening of diabetes symptoms, and persons with diabetes are at increased risk for severe COVID-19. SARS-CoV-2 infection might also induce newly diagnosed diabetes. Persons aged <18 years with COVID-19 were more likely to receive a new diabetes diagnosis >30 days after infection than were those without COVID-19 and those with pre-pandemic acute respiratory infections. Non–SARS-CoV-2 respiratory infection was not associated with an increased risk for diabetes. The increased diabetes risk among persons aged <18 years following COVID-19 highlights the importance of COVID-19 prevention strategies in this age group, including vaccination for all eligible persons and chronic disease prevention and treatment.</u>

Other Resources and Guidance

Reducing Stigma for Testing Positive for COVID-19: <u>Stigma</u> can negatively affect the emotional, mental, and physical health of stigmatized groups and the communities they live in. Stigmatized individuals may experience isolation, depression, anxiety, or public embarrassment. Stopping stigma is important to making *all* communities and community members safer and healthier. Everyone can help stop stigma related to COVID-19 by <u>knowing the facts</u> and sharing them with others in their communities. <u>A guide to preventing and addressing social stigma</u> associated with COVID-19 can be found here. Additional resources

Travel-Associated Exposure: CDC <u>updated their information on travel-associated exposures</u>. Specifically, CDC aligned their information with current CDC guidance for avoiding travel after ending isolation and quarantine, as well as CDC guidance for travelers based on up-to-date vaccination status.

Potential Exposure at Work: The CDC <u>updated their guidance on protocol following potential exposure at work.</u> Due to concerns about increased transmissibility of the SARS-CoV-2 Omicron variant, this guidance is being updated to enhance protection for healthcare personnel (HCP), patients, and visitors, and to address concerns about potential impacts on the healthcare system given a surge of SARS-CoV-2 infections. These updates will be refined as additional information becomes available to inform recommended actions. In general, asymptomatic HCP who have recovered from SARS-CoV-2 infection in the prior 90 days do not require work restriction following a higher-risk exposure.

CDC Guidance Regarding Staffing Shortages: The CDC <u>released updated guidance regarding</u> <u>staff shortages</u>. Specifically, due to concerns about increased transmissibility of the SARS-CoV-2 Omicron variant, this guidance is being updated to enhance protection for healthcare personnel (HCP), patients, and visitors and to address concerns about potential impacts on the healthcare

system given a surge of SARS-CoV-2 infections. These updates will be refined as additional information becomes available to inform recommended actions.

Guidance on Ending Isolation and Precautions for People with COVID-19: CDC <u>updated</u> guidance on ending isolation and precautions for people with <u>COVID-19</u>. Specifically, CDC released updated guidelines to reflect new recommendations on isolation for people with COVID-19 and added new recommendations for duration of isolation for people with COVID-10 who are moderately or severely immunocompromised.

CDC Updates Consumer Mask Website to Emphasize Protection, Fit, and Comfort: CDC has updated the consumer webpage describing the types of masks and respirators used to prevent the transmission of SARS-CoV-2. The updated page lays out the protection provided by available masks and respirators, noting that some provide better protection than others. These updates to CDC's webpage reflect the science on masking, including what we have learned in the past two years, and will provide people the information they need to improve how well their masks or respirators protect them. The CDC will continue to share the science of masking as it becomes available.

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

Tribal Affairs Team

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