January 11, 2022

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

Please see the attached Dear Tribal Leader Letter requesting nominations for Tribal Leaders to serve on the HHS Secretary's Tribal Advisory Committee. All nominees must either be elected or appointed tribal officials acting in their official capacity as elected officials of their tribes, or be designated by an elected tribal official with the designee having authority to act on behalf of the tribal official. Nominations *must be* made by an elected or appointed official from a federally recognized tribe acting in his or her official capacity. We encourage you to submit your nomination letter, no later than February 16, 2022 to <u>STAC@hhs.gov</u>. More information about the STAC can be found <u>here</u>.

HHS Tribal Consultation Updates

Assistant Secretary for Planning and Evaluation (ASPE): Acting Assistant Secretary for Planning and Evaluation Rebecca Haffajee announced an extension of the comment period for Tribal Consultation on the <u>draft HHS Strategic Plan for FY 2022-2026</u>. HHS values its government-togovernment relationship with Indian Tribes and recognizes that robust Tribal Consultation is important to this process. In response to requests for additional time to provide comments, HHS has extended the Tribal Consultation period and is hosting a virtual consultation session on January 13th at 1:00 – 3:00 PM ET. You can <u>register here</u>.

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 was <u>published</u> in the Federal Register on December 6, 2021. Below is the Dear Tribal Leader Letter (DTLL) from FDA Deputy Commissioner for Food Policy and Response Frank Yiannas that invites you or your designated consultation official to a conference call on February 4, 2022 at 1:00 PM ET. The DTLL also contains background on the proposed rule, and can be accessed as a PDF on our website <u>here</u>.

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 (AI/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.

Departmental Updates

National Plan to Address Alzheimer's Disease: The Department of Health and Human Services released the annual update to its *National Plan to Address Alzheimer's Disease*, which

for the first time includes a new goal focused on work being done to promote healthy aging and reduce the risks that may contribute to the onset of Alzheimer's disease and related dementias. Although these diseases cannot yet be prevented, there is growing evidence that addressing certain risk factors for dementia, such as high blood pressure, physical inactivity, and chronic medical conditions, such as diabetes and depression, may lower the chances of developing the disease or delay its onset.

Indian Health Service (IHS) Update: The <u>White House declared</u> January as National Human Trafficking Prevention Month. The IHS, the Administration for Native Americans, and the CDC partnered to develop a Domestic Violence Awareness Public Service Announcement campaign, tailored specifically for Native communities for the purposes of providing survivors access to resources, improving bystanders' ability to safely intervene, and increasing prevention efforts on both the individual and community level. These Public Service Announcements are a culmination of a federal interagency effort to support domestic violence prevention efforts and healing within Native communities, and I encourage you to share them widely.

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

The IHS <u>TeleBehavioral Health Center of Excellence</u> will host the following webinars for health care providers in January:

- "Child and Adolescent Behavioral Health Webinar Series: Autism Spectrum Disorder & Mood Disorders" on January 13 at 3:00 PM ET. Please follow this <u>link</u> to register.
- "Addictions and Recovery Webinar Series: Inhalant Use Disorder" on January 18 at 12:00 PM ET. Please follow this <u>link</u> to register.

Centers for Medicare and Medicaid Services (CMS): CMS <u>released guidance on the Omnibus</u> <u>COVID-19 Health Care Staff Vaccination Interim Final Rule</u> that was published on November 5, 2021. The emergency regulation helps safeguard health care workers and the people they serve from COVID-19 and its variants for all individuals seeking care by imposing requirements regarding vaccinations for eligible staff at health care facilities participating in the Medicare and Medicaid programs. This guidance provides important information on implementation, as well as guidelines to assess and maintain compliance with the COVID-19 vaccination requirements for health care workers at facilities participating in the Medicare and Medicaid programs.

Office of Minority Health (OMH) Update: OMH is recruiting primary and alternate delegates for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee (CIIHE

TAC), in alignment with the 12 geographic areas served by the Indian Health Service. Information about CIIHE TAC membership can be found here: <u>American Indian/Alaska Native -</u> <u>The Office of Minority Health (hhs.gov)</u>, including eligibility requirements, selection criteria, and nomination procedures. OMH has extended the deadline date for submission for nominations published in the <u>Federal Register (86 FR 64951)</u> from October 29 to March 11, 2022 at 11:59 PM EST.

We strongly encourage interested tribal leaders or designated tribal representatives to submit their nomination letter before the extended deadline. Information about CIIHE TAC membership can be found here: <u>American Indian/Alaska Native - The Office of Minority Health</u> (<u>hhs.gov</u>), including eligibility requirements, selection criteria, and nomination procedures and template letters. *We request you reach out to your respective tribes and tribal organizations. We also strongly encourage you to submit your nomination letter before this extended deadline*.

If you have questions about the nomination process for delegates, please contact Violet Woo, Designated Federal Official, at <u>Violet.Woo@hhs.gov</u>. For all other questions related to Tribal Affairs, please contact CAPT Damion Killsback, OMH Senior Advisor for Tribal Affairs, at <u>Damion.Killsback@hhs.gov</u>.

The Centers for Disease Control and Prevention (CDC) Update: The Centers for Disease Control and Prevention (CDC) is working with the National Indian Health Board to better understand and amplify the ways in which AI/AN mothers, partners, caregivers, and community members can best keep mothers and babies healthy and safe during pregnancy and beyond. It is essential to work together to protect native families and communities. Please join CDC and NIHB on January 27 at 1:00 – 2:30 PM ET for a special discussion session on a new campaign segment aimed to support AI/AN healthy pregnancies and postpartum health, based on the existing Hear Her campaign. During the session, CDC speakers will provide a brief overview of the campaign. You can register <u>here</u>.

Food and Drug Administration (FDA) Update: The FDA has a number of American Indian and Alaska specific resources on COVID-19, including <u>fact sheets</u> for recipients and caregivers translated in multiple languages, including Navajo and Cherokee. In addition, FDA has several <u>multilingual social media toolkits</u>. FDA's Office of Minority Health and Health Equity also has a number of <u>resources specific to Native American Communities, including information and</u> <u>videos in Navajo and Cherokee.</u>

Vaccines

FDA Shortens Interval for Booster Dose of Moderna COVID-19 Vaccine to Five Months: On Friday, the U.S. Food and Drug Administration <u>amended the emergency use authorization (EUA)</u> for the Moderna COVID-19 Vaccine to shorten the time between the completion of a primary series of the vaccine and a booster dose to at least five months for individuals 18 years of age and older. Read the <u>CDC Media Statement here</u>.

CDC Recommends Pfizer Booster at 5 Months, Additional Primary Dose for Certain Immunocompromised Children: Last week, CDC <u>updated its recommendation for when many</u> <u>people can receive a booster shot</u>, shortening the interval from 6 months to 5 months for people who received the Pfizer-BioNTech COVID-19 Vaccine. This means that people can now receive an mRNA booster shot 5 months after completing their Pfizer-BioNTech primary series. The booster interval recommendation for people who received the J&J vaccine (2 months) or the Moderna vaccine (6 months), has not changed. Additionally, consistent with our prior recommendation for adults, CDC is recommending that moderately or severely immunocompromised 5–11-year-olds receive an additional primary dose of vaccine 28 days after their second shot. At this time, only the Pfizer-BioNTech COVID-19 vaccine is authorized and recommended for children aged 5-11.

Testing, Tracing, and Treatment

Biden-Harris Administration Requires Insurance Companies and Group Health Plans to Cover the Cost of At-Home COVID-19 Tests, Increasing Access to Free Tests: As part of its ongoing efforts across many channels to expand Americans' access to free testing, the Biden-Harris Administration <u>is requiring insurance companies and group health plans</u> to cover the cost of over-the-counter, at-home COVID-19 tests, so people with private health coverage can get them for free starting January 15th. The new coverage requirement means that most consumers with private health coverage can go online or to a pharmacy or store, buy a test, and either get it paid for up front by their health plan, or get reimbursed for the cost by submitting a claim to their plan. This <u>requirement</u> incentivizes insurers to cover these costs up front and ensures individuals do not need an order from their health care provider to access these tests for free.

CDC Updates and Shortens Recommended Isolation and Quarantine Period for General Population: Given what we currently know about COVID-19 and the Omicron variant, CDC <u>is</u> <u>shortening the recommended time for isolation</u> for the public. People with COVID-19 should isolate for 5 days and if they are asymptomatic or their symptoms are resolving (without fever for 24 hours), follow that by 5 days of wearing a mask when around others to minimize the risk of infecting people they encounter. The change is motivated by science demonstrating that the majority of SARS-CoV-2 transmission occurs early in the course of illness, generally in the 1-2 days prior to onset of symptoms and the 2-3 days after.

FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults: On December 23, the U.S. Food and Drug Administration <u>issued an emergency use authorization</u> (EUA) for Merck's molnupiravir for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. Molnupiravir is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset. Molnupiravir is not authorized for use in patients younger than 18 years of age because molnupiravir may affect

bone and cartilage growth. It is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in patients hospitalized due to COVID-19 because benefit of treatment has not been observed in people when treatment started after hospitalization due to COVID-19.

Two New Over-the-Counter At-Home COVID-19 Tests Brought to U.S. Market Quickly by Biden-Harris Administration: The Biden-Harris Administration <u>has brought two new over-the-</u> <u>counter, at-home COVID-19 tests to the U.S. market</u>. The tests, one manufactured by SD Biosensor and distributed by Roche and the other manufactured by Siemens, have received emergency use authorization (EUA) by the Food and Drug Administration (FDA) after being evaluated through the Administration's new accelerated pathway to support FDA review of tests with potential for large-scale manufacturing that the Department of Health and Human Services (HHS) announced just two months ago. These quick authorizations are thanks to collaboration between the FDA and the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics Technology (RADx) program. Combined, it is estimated the companies can produce tens of millions of tests per month for use in the U.S.

Use of Masks to Control the Spread of SARS-CoV-2: CDC <u>updated a study on the use of masks</u> to control the spread of COVID-19. Data was added from recently published studies that addressed the association of mask wearing with new infections, including infections related to SARS-CoV-2 variants of concern. All studies demonstrated a benefit of people of all ages wearing masks to prevent transmission.

Research

Severe COVID-19 Outcomes Among Persons Aged 18 And Older Who Completed a Primary COVID-19 Vaccination Series: CDC released an *MMWR* on <u>severe COVID-19 outcomes among</u> persons aged 18 and older who completed a primary COVID-19 vaccination series in 465 health care facilities in the United States between December 2020 – October 2021. COVID-19 vaccines are highly effective against COVID-19 associated hospitalization and death. Among 1,228,664 persons who completed primary vaccination during December 2020 – October 2021, severe COVID-19- associated outcomes (0.015%) or death (0.0033%) were rare. Risk factors for several outcomes included ages 65 and older, immunosuppressed, and six other underlying conditions. All persons with severe outcomes had at least one risk factor; 78% of persons who had died had at least four. Vaccinated persons who are older, immunosuppressed, or have other underlying conditions should receive targeted interventions to include chronic disease management, precautions to reduce exposure, additional primary booster vaccination doses, and effective pharmaceutical therapy to mitigate risk for severe outcomes. Increasing vaccination coverage is a critical public health priority.

COVID-19 Vaccine Safety in Children Aged 5–11 Years: CDC released an *MMWR* on <u>COVID-19</u> <u>vaccine safety in children aged 5-11 years</u> in the United States between November 3 – December 9, 2021. In preauthorization trials for Pfizer-BioNTech (BNT162b2) COVID-19 vaccine, vaccinated children aged 5–11 years reported mild to moderately severe local and systemic reactions; no serious vaccination-related events were noted. After authorization of Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years during October 2021, and administration of approximately 8 million doses, local and systemic reactions after vaccination were commonly reported to VAERS and v-safe for vaccinated children aged 5–11 years. Serious adverse events were rarely reported. Parents and guardians of children aged 5–11 years should be advised that local and systemic reactions are expected after vaccination with Pfizer-BioNTech COVID-19 vaccine and are more common after the second dose.

Evaluation of a Test to Stay Strategy in Transitional Kindergarten Through Grade 12 Schools: CDC released an *MMWR* on <u>an evaluation of the test to stay strategy in transitional</u> <u>kindergarten through grade 12 schools</u> in Los Angeles County, California between august 16 – October 31, 2021. Los Angeles County Department of Public Health permits Test to Stay (TTS) as a COVID-19 quarantine strategy that allows students with school exposures to remain in school if both infected and exposed persons wore masks. One in five LAC public schools adopted TTS. In TTS schools, student case rates did not increase, and tertiary transmission was not identified. A higher percentage of disadvantaged schools did not implement TTS. TTS does not appear to increase transmission risk in public schools and might greatly reduce loss of in-person school days. Implementation requires resources that might be currently unavailable for some schools. Vaccination remains the leading recommendation to protect against COVID-19; TTS allows students with a school exposure to remain in the classroom as an alternative to home quarantine.

Evaluation of Test to Stay Strategy on Secondary and Tertiary Transmission of SARS-CoV-2 in K–12 Schools: CDC released an *MMWR* on <u>an evaluation of the test to stay strategy on</u> <u>secondary and tertiary transmission of SARS-CoV-2 in K-12 schools</u> in Lake County, Illinois between August 9 – October 29, 2021. COVID-19 transmission within K–12 schools can remain low with implementation of multiple, concurrent prevention strategies. During fall 2021, 90 Lake County, Illinois, schools implemented Test to Stay (TTS), permitting eligible close contacts with masked COVID-19 exposures to remain in school. Secondary transmission among TTS participants was 1.5%; no tertiary transmission was observed among school-based contacts; however, tertiary cases were identified among household contacts. Implementation of TTS preserved up to 8,152 in-person learning days. Although vaccination remains the leading recommendation to protect against COVID-19, TTS allows close contacts to remain in the classroom as an alternative to home guarantine.

Investigation of a SARS-CoV-2 B.1.1.529 (Omicron) Variant Cluster: CDC released an *MMWR* on <u>an investigation of a SARS-CoV-2 B.1.1.529 (Omicron) variant cluster</u> in Nebraska from November – December 2021. On November 29, the Nebraska Department of Health and Human Services was notified of six probable cases of COVID-19 in one household, including one case in a man aged 48 years (the index patient) who had recently returned from Nigeria. On November 24, 2021, the index patient experienced symptoms consistent with COVID-19§§ and initially received a positive SARS-CoV-2 antigen test result from a local medical center on November 26. All six household members (median age = 18.5 years; range = 11–48 years) experienced symptom onset during November 24–26; median interval between earliest

possible exposure to the index patient and symptom onset was 73 hours (range = 33–75 hours). The index patient and the four household contacts with previous confirmed infections described the symptoms and severity of their recent COVID-19 infection as being similar to or milder than those during their first infection. The five reinfected patients experienced fewer current symptoms, including loss of taste (none), loss of smell (none), and subjective fever (two), compared with symptoms reported during their first infections (four, four, and four, respectively). The unvaccinated patient without a previous COVID-19 diagnosis experienced cough, joint pain, congestion, fever, and chills. None required hospitalization for either their first or second infections. Twelve close community contacts of the family were identified. Four consented to testing for SARS-CoV-2 (median of 10.5 days postexposure; range = 10–11 days); specimens from these four close contacts tested negative.

Understanding the Long-Term Effects of COVID-19 in Children: NIH <u>released an article on</u> <u>understanding the long-term effects of COVID-19 in children</u>. As of November 2021, more than 6 million children in the United States have tested positive for COVID-19. To better understand COVID-19's impact on children, a long-term study supported by NIH's REsearching COVID to Enhance Recovery (RECOVER) Initiative will follow up to 1,000 children who had previously tested positive for COVID-19 over 3 years. Researchers will monitor the participants' health to build a thorough picture of COVID-19's long-term impacts on children.

Other Resources and Guidance

Guidance for COVID-19 Prevention in K-12 Schools: The CDC <u>updated guidance for COVID-19</u> <u>prevention for K-12 schools</u>. Specifically, the CDC guidance reflects new recommendations for isolation for people with COVID-19, and recommendations for people who have come into close contact with a person with COVID-19.

Public Health Guidance for Potential COVID-19 Exposure Associated with Travel: CDC <u>updated</u> <u>its public health guidance</u> for potential COVID-19 exposure associated with travel. Specifically, the guidance aligned with CDC quarantine and isolation guidance, and removed information about CDC's November 30, 2021, Directive to airlines to provide passenger contact information.

CDC Releases Emergency Guidance for Healthcare Facilities to Prepare for Potential Omicron Surge: With the growing number of COVID-19 cases from the Omicron variant, and consistent with current understanding of the disease trajectory, CDC <u>is releasing updated guidance for</u> <u>isolation and quarantine for healthcare workers</u>, decreasing their isolation time after infection with COVID-19. Additionally, CDC is releasing an update to guidance for contingency and crisis management in the setting of significant healthcare worker shortages. These updates provide healthcare facilities with the strategies to limit the effects of staff shortages caused by COVID-19 on patient care and note that:

• Healthcare workers with COVID-19 who are asymptomatic can return to work after 7 days with a negative test, and that isolation time can be cut further if there are staffing shortages.

Healthcare workers who have received all recommended COVID-19 vaccine doses, including a booster, do not need to quarantine at home following high-risk exposures.

Strategies to Mitigate Healthcare Personnel Staffing Shortages: CDC <u>updated its strategies to</u> <u>mitigate healthcare personnel staffing shortages</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.

- Ensure that SARS-CoV-2 testing is performed with a test that is capable of detecting SARS-CoV-2, even with the currently circulating variants in the United States.
- Updated contingency and crisis strategies for mitigating staff shortages.

Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2: CDC updated its interim guidance for managing healthcare personnel with SARS-CoV-2 infection or exposure to SARS-CoV-2. 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.

- Ensure that SARS-CoV-2 testing is performed with a test that is capable of detecting SARS-CoV-2, even with currently circulating variants in the United States.
- Updated recommendations regarding when HCP with SARS-CoV-2 infection could return to work
- The definition of higher-risk exposure was updated to include use of a facemask (instead of a respirator) by HCP if the infected patient is not also wearing a facemask or cloth mask.
- Added options that would allow asymptomatic HCP with a higher-risk exposure who have not received all COVID-19 vaccine doses, including booster dose, as recommended by CDC to return to work prior to the previously recommended 14-day post-exposure period of work restriction, assuming they do not develop symptoms or test positive for SARS-CoV-2.

COVID-19 and Social Media: On January 20 at 1:00 PM ET, the CDC Foundation will be hosting a webinar discussing strategies to better utilize social media to engage your community with COVID-19 related content and resources. During this 60-minute interactive webinar hosted by <u>the CDC Foundation's Community COVID Coalition</u> in partnership with <u>Vaccine Equity</u>

<u>Cooperative</u>, experts will answer your most pressing questions on effective social media communication strategies and share the best practices for leveraging social media in your community -- especially with limited resources and small budgets. Two local communities will also highlight equity-centered approaches that ensure public health communications reach our most vulnerable populations, feature culturally competent content and resources, and combat misinformation.

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

Tribal Affairs Team

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