

**June 22, 2021**

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

Last week, the U.S. Supreme Court upheld the Affordable Care Act (ACA) by a vote of 7 to 2. This is the third challenge to the law that has provided over 31 million Americans with access to health insurance. “[Last week’s] decision means that all Americans continue to have a right to access affordable care, free of discrimination. More than 133 million people with pre-existing conditions, like cancer, asthma or diabetes, can have peace of mind knowing that the health protections they rely on are safe,” said HHS Secretary Xavier Becerra. “Individuals who have faced discrimination can continue accessing care without fear. And people relying on Medicaid and Medicare should know these programs are stronger than ever.”

The ACA also includes permanent reauthorization of the Indian Health Care Improvement Act, which is the cornerstone legal authority for the provision of health care to American Indians and Alaska Natives.

### **HHS Tribal Consultation Updates**

**HHS Annual Regional Tribal Consultations:** This summer, HHS will continue to hold [HHS Regional](#) Tribal Consultation Sessions. These sessions provide Tribes opportunities to focus on regional specific issues with their respective regional HHS counterparts, and also provides an opportunity for Tribal Leaders to consult with HHS headquarters leadership on issues at the national level. The schedule and registration links are below:

- June 29, 2021: **Region 3**

<https://www.zoomgov.com/meeting/register/vJlSfuitpzltHskQvNmmTZrYX5PW9lswfMo>

Contact: Melissa Herd; [Melissa.Herd@hhs.gov](mailto:Melissa.Herd@hhs.gov)

- July 21 – 22, 2021: **Region 5**

<https://www.zoomgov.com/meeting/register/vJltduurzgiGO90M4liEf75OXfauI5zLCY>

Contact: Sam Gabuzzi; [Sam.Gabuzzi@hhs.gov](mailto:Sam.Gabuzzi@hhs.gov)

- July 27, 2021: **Region 1**

<https://www.zoomgov.com/meeting/register/vJlscuugqTIsHnUWRonprwUgGjND0pgUUKU>

Contact: Paul Jacobsen; [Paul.Jacobsen@hhs.gov](mailto:Paul.Jacobsen@hhs.gov)

- August 9 – 12, 2021: **Region 9**

<https://www.zoomgov.com/meeting/register/vJlsdOyppjsuGpV6VYabm6IYwGDBaQVQvY>

Contact: Schuyler Hall; [Schuyler.Hall@hhs.gov](mailto:Schuyler.Hall@hhs.gov)

**ACF Head Start:** The Office of Head Start (OHS) has scheduled four Tribal Consultation sessions. These one-day sessions will be held between U.S. Department of Health and Human Services (HHS), Administration for Children and Families (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 1–5: Wednesday, July 7, 2021, 1–4 p.m. ET
- Geographic Regions 6–8: Wednesday, Aug. 18, 2021, 1–4 p.m. ET
- Geographic Regions 9–10: Tuesday, Sept. 21, 2021, 2–5 p.m. ET
- National: Monday, Nov. 15, 2021, 1–4 p.m. ET

Additional information can be found on the [ELCKC website](#). To register, click here:

<https://cvent.me/5x94xk>

### **Departmental Updates**

**Indian Health Service Update:** The IHS [sent letters to Tribal Leaders and Urban Indians Organization Leaders](#) to announce the allocation decisions for approximately \$1.8 billion in resources appropriated to the IHS in the American Rescue Plan Act, 2021 (ARPA). This is in addition to an allocation of approximately \$4.3 billion in ARPA funds that was [announced in April 2021](#). These allocation decisions were made following tribal consultation and urban confer regarding the allocation of \$6.094 billion in ARPA resources. This investment from the APRA will strengthen the public health workforce in Indian Country, support mental health and substance abuse prevention and treatment, continue efforts to detect and treat COVID-19, and meet facility and equipment needs related to the COVID-19 pandemic.

The IHS remains focused on adult vaccination rates and progress in meeting the President’s goal, calling for 70 percent of adults to get at least one shot by July 4th. To date, over 1.4 million vaccine doses have been administered across the Indian health system by those sites that received their doses from IHS. And over 53 percent of American Indian and Alaska Native adult patients have received at least one vaccine dose. The IHS has updated their [COVID-19 Positive Cases by IHS Area](#) and this dashboard will be updated on a weekly basis.

**ACF Update:** The Department of Health and Human Services (HHS), through the Administration for Children and Families (ACF), released \$994.5 million from the Pandemic Emergency Assistance Fund (PEAF) to assist needy families impacted by the COVID-19 pandemic. States, the District of Columbia, tribes operating a Tribal Temporary Assistance for Needy Families (TANF) program, and all five U.S. territories were eligible to receive funds; all but one of these 131 eligible entities requested funds and received their maximum allotments. [Visit the Office of Family Assistance for more information.](#)

**HRSA Update:** HRSA announced that the HRSA COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured has paid over 5 million claims to health care providers for administering COVID-19 vaccines to uninsured individuals. HRSA also recently launched the [COVID-19 Coverage Assistance Fund](#), which covers the costs of COVID-19 vaccines for uninsured patients.

**CDC Update:** On Wednesday, June 30, 2021, the National Indian Health Board (NIHB) in coordination with the Centers for Disease Control and Prevention (CDC), will be hosting an Infectious Disease Preparedness Learning Community (IDPLC) Informational Webinar from 3:00pm to 4:00pm EST. The IDPLC will meet once a month to discuss guidelines, best practices, and lessons learned for the prevention and control of present and future infectious disease outbreaks in Tribal communities as well as guidelines and strategies shared by the CDC. To register, please click here: [https://us02web.zoom.us/webinar/register/WN\\_P6cDI-voR9K651g4CUPMgw](https://us02web.zoom.us/webinar/register/WN_P6cDI-voR9K651g4CUPMgw)

**FDA Update:** The FDA updated its FDA COVID-19 Response [At-A-Glance Summary](#), which provides a quick look at facts, figures and highlights on the FDA's response efforts.

### **Vaccine Updates**

**U.S. Clinical Trial Results Show Novavax Vaccine is Safe and Prevents COVID-19:** NIH's National Institute of Allergy and Infectious Diseases [released results from a Phase 3 clinical study](#). The study enrolled 29,660 adult volunteers in the United States and Mexico and found that the investigational vaccine known as NVX-CoV2373 demonstrated 90.4% efficacy in preventing symptomatic COVID-19 disease. The candidate showed 100% protection against moderate and severe disease. In people at high risk of developing complications from COVID-19 (people 65 years or older and people under age 65 with certain comorbidities or with likely regular exposure to COVID-19), the vaccine showed 91.0% efficacy in preventing symptomatic COVID-19 disease. Safety data indicate the investigational vaccine was generally well-tolerated.

Mild-to-moderate injection site pain and tenderness were the most common local symptoms among participants, and fatigue, headache and muscle pain lasting less than two days were the most common systemic symptoms.

**CDC COVID-19 Study Shows mRNA Vaccines Reduce Risk of Infection by 91 Percent for Fully Vaccinated People:** A new CDC study [finds the mRNA COVID-19 vaccines authorized by the Food and Drug Administration \(Pfizer-BioNTech and Moderna\)](#) reduce the risk of infection by 91 percent for fully vaccinated people. This adds to the growing body of real-world evidence of their effectiveness. Importantly, this study also is among the first to show that mRNA vaccination benefits people who get COVID-19 despite being fully vaccinated (14 or more days after dose 2) or partially vaccinated (14 or more days after dose 1 to 13 days after dose 2). The findings come from four weeks of additional data collected in CDC's HEROES-RECOVER study of health care workers, first responders, frontline workers, and other essential workers. These groups are more likely to be exposed to the virus that causes COVID-19 because of their occupations. Preliminary results from this study were first announced in March 2021.

**FDA Takes Steps to Increase Availability of COVID-19 Vaccine:** Following careful review and deliberation, the U.S. Food and Drug Administration is [taking important steps that will allow a critically needed supply of the Janssen \(Johnson & Johnson\) COVID-19 Vaccine to be made available](#). The agency announced recently that it is authorizing for use, under the emergency use authorization (EUA) for the Janssen COVID-19 vaccine, two batches of vaccine drug substance manufactured at the Emergent BioSolutions facility in Baltimore. Before making this decision, the FDA conducted a [thorough review](#) of facility records and the results of quality testing performed by the manufacturer. Based on this review and considering the current COVID-19 public health emergency, the FDA concluded these batches are suitable for use. While the FDA is not yet ready to include the Emergent BioSolutions plant in the Janssen EUA as an authorized manufacturing facility, the agency continues to work through issues there with Janssen and Emergent BioSolutions management.

**COVID-19 Vaccines:** CDC [updated their Key Things to Know page on the COVID-19 vaccine](#). The page outlines the availability of vaccines, vaccine effectiveness, vaccine safety, population immunity, and new variants. CDC [updated their COVID-19 vaccine frequently asked questions page](#). CDC also [updated their information on the Moderna vaccine](#), providing a safety data summary, how well the vaccine works, and clinical trial demographic information.

**Reported Adverse Events:** CDC [updated their information and data on reported adverse events from the COVID-19 vaccine](#) through the Vaccine Adverse Event Reporting System (VAERS). As of June 7, 2021, more than 11.2 million doses of the J&J/Janssen COVID-19 Vaccine have been

given in the United States. CDC and FDA identified 35 confirmed reports of people who got the J&J/Janssen COVID-19 Vaccine and later developed TTS. There is a plausible causal relationship between J&J/Janssen COVID-19 Vaccine and TTS. Women younger than 50 years old especially should be aware of the rare but increased risk of this adverse event. As of June 9, 2021, VAERS has received 623 reports of myocarditis or pericarditis among people ages 30 and younger who received COVID-19 vaccine. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults. Through follow-up, including medical record reviews, CDC and FDA have confirmed 268 reports of myocarditis or pericarditis.

**Updates to Clinic Portal:** CDC [updated the clinic portal to streamline processes, consolidating and rearranging various tabs](#). CDC also created a [guide which Americans may follow with steps to register and schedule vaccination appointments for themselves or on behalf of others](#) within the updated portal. The page provides a quick reference guide with instructions for using the guest registration functionality in Vaccine Administration Management System (VAMS) to schedule vaccination appointment(s) and register for a vaccine.

**CDC's COVID-19 Partner Calls:** CDC updated their [information for community-based calls](#) wherein representatives for community organizations, local government, the private sector, academia, and the general public can learn how to help slow the spread of COVID-19. The next call – A call to action: Mobilizing America to Vaccinate Against COVID-19 – will be on June 21.

**Updated Translations for Pfizer-BioNTech Fact Sheet:** The FDA recently posted the updated translations for the Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Recipients and Caregivers in multiple languages. The translations can be found [here](#).

**Variant of Concern:** CDC is [tracking a new variant of the virus that causes COVID-19 called Delta, or B.1.617.2](#). There is evidence that this variant spreads easily from person to person. This variant is classified as a variant of concern, which is a variant for which there is evidence of an increase in transmissibility, more severe disease (e.g., increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures.

**COVID-19 Vaccines for People with Underlying Medical Conditions:** CDC updated their [information on COVID-19 vaccines for individuals with underlying medical conditions](#). Specifically, CDC updated guidance for people living with HIV and those with weakened immune systems that, if they have a condition or are taking medications that weaken your immune system, they may NOT be fully protected even if you are fully vaccinated; they should talk to

their healthcare provider and, even after vaccination, they may need to continue taking all [precautions](#).

**COVID-19 Vaccines While Pregnant or Breastfeeding:** CDC [updated their information on the COVID-19 vaccines for people who are pregnant or breastfeeding](#). Pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people. If you are pregnant, you can receive a COVID-19 vaccine.

## **Testing and Treatment**

**Overview of Testing for SARS-CoV-2:** CDC [added a new webpage explaining the COVID-19 Viral Testing Tool](#), an interactive web tool designed to help both healthcare providers and individuals understand COVID-19 testing options and which choice might be right for each person. CDC updated the following pages with this resource: [Testing Resources](#), [Testing Overview](#), [Guidance for Rapid Antigen Testing for SARS-CoV-2](#), [Nucleic Acid Amplification Tests](#), [Guidance for SARS-CoV-2 Point-of-Care Testing](#), and [Guidance for Healthcare Workers about COVID-19 Testing](#).

**Innova SARS-CoV-2 Antigen Rapid Qualitative Test:** On June 10, the FDA [issued a safety communication warning the public](#) to stop using the Innova SARS-CoV-2 Antigen Rapid Qualitative Test for diagnostic use. The FDA has significant concerns that the performance of the test has not been adequately established, presenting a risk to health. In addition, the test labeling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during the clinical studies of the tests. Finally, the test has not been authorized, cleared or approved by the FDA for commercial distribution or use in the United States, as required by law.

**FDA Testing Updates:** As of Friday, [384 tests and sample collection devices are authorized by the FDA under emergency use authorizations \(EUAs\)](#). These include 275 molecular tests and sample collection devices, 81 antibody and other immune response tests and 28 antigen tests. There are 52 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, five antigen over-the-counter (OTC) at-home tests and two molecular OTC at-home tests. The FDA has authorized 11 antigen tests and three molecular tests for serial screening programs. The FDA has also authorized 532 revisions to EUA authorizations.

## **Funding**

**HHS Provides \$424.7 Million to Rural Health Clinics for COVID-19 Testing and Mitigation in Rural Communities:** On Friday, thanks to the American Rescue Plan, the U.S. Department of Health and Human Services (HHS) through the Health Resources and Services Administration (HRSA) [provided \\$424.7 million in funding to over 4,200 Rural Health Clinics \(RHCs\) for COVID-19 testing and mitigation.](#) Later this summer, HRSA will issue up to \$35.3 million in additional funding to RHCs that meet eligibility requirements. HRSA is funding RHCs based on the number of certified clinic sites they operate, providing \$100,000 per clinic site. RHCs will use the funds to maintain and increase COVID-19 testing, expand access to testing for rural residents, and broaden efforts to mitigate the spread of the virus in ways tailored to their local communities. Rural Health Clinics are key health care access points and trusted community resources. They have a special designation given to health care practices in underserved rural areas by the Centers for Medicare & Medicaid Services to help ensure access to care for rural residents.

**American Rescue Plan Act Emergency Native Language Funding Opportunity Deadline:** The Administration for Children and Families (ACF) has a non-competitive award deadline that is due on Friday, June 25, 2021 by 11:59pm EST. The ARP Emergency Grants for Native American Language Preservation and Maintenance will provide appropriations to support Native American languages. The following link provides an instructional webinar regarding the grant: <https://www.anawestern.org/webinars>

**SAMHSA Awards Vibrant Grant to Administer National Suicide Prevention Lifeline 988:** The Substance Abuse and Mental Health Services Administration (SAMHSA) [announced Vibrant Emotional Health \(Vibrant\) will be the administrators of the new 988 dialing code for the National Suicide Prevention Lifeline \(Lifeline\).](#) A pair of the agency's grants, totaling **\$48 million** and including \$32 million in Coronavirus Response and Relief Supplemental Appropriations Act, 2021 funding, will fund the effort to better harness technology to help Americans in mental health crises and save more lives. The requirement for phone service providers to transition to 988 as the National Suicide Prevention Lifeline will take effect on July 16, 2022.

**The Biden Administration announced an investment of \$3 billion from the American Rescue Plan as a part of the COVID-19 Antiviral Development Strategy:** Through a collaboration within the U.S. Department of Health and Human Services, including the National Institutes of Health (NIH) and its National Institute of Allergy and Infectious Diseases (NIAID), the Antiviral Program for Pandemics will respond to the urgent need for antivirals to treat COVID-19. "New antivirals that prevent serious COVID-19 illness and death, especially oral drugs that could be taken at home early in the course of disease, would be powerful tools for battling the pandemic and saving lives," said Dr. Anthony Fauci, chief medical adviser to the President and NIAID Director. "Through multidisciplinary collaborations among leading scientists in academia and industry,

this investment from the American Rescue Plan to create the Antiviral Program for Pandemics will help inspire medical innovation and build on the extraordinary success we have seen in developing the COVID-19 vaccines.”

## **Data**

The CDC [released their COVID-19 data tracker weekly review](#). CDC updated their data on reported cases, SARS-CoV-2 variants, testing, vaccinations, hospitalizations, and deaths. CDC also posted recent CDC COVID-19 publications. The weekly review contained specific analysis on how long-standing systemic health and social inequities have put many people from racial and ethnic minorities at increased risk. Particularly, CDC highlighted a recent rise in hospitalization rates for Non-Hispanic American Indian and Alaskan Native People populations amidst a universal decrease in all other populations. CDC also added new information to their COVID-19 data tracker. CDC [added a new nationwide blood donor seroprevalence tab](#) to display estimates of the percent of people with antibodies against SARS-CoV-2 from a study of blood donors.

CDC [added a new health equity landing page that catalogs health equity-related data available](#). Furthermore, CDC [added emergency department visit trends information to the daily and total trends tab](#).

## **Research**

**How COVID-19 Can Lead to Diabetes:** NIH Director Dr. Francis Collins [comments on two studies that explore how COVID-19 can lead to diabetes](#). Type 1 diabetes occurs when beta cells in the pancreas don't secrete enough insulin to allow the body to metabolize food optimally after a meal. As a result of this insulin insufficiency, blood glucose levels go up, the hallmark of diabetes. SARS-CoV-2 can infect human beta cells, and further replicate in these insulin-producing beta cells, to make more copies of itself and spread to other cells. Moreover, the studies found that the coronavirus infection changes the function of islets — the pancreatic tissue that contains beta cells. Both research teams report evidence that infection with SARS-CoV-2 leads to reduced production and release of insulin from pancreatic islet tissue. In addition to the loss of beta cells, the infection also appears to change the fate of the surviving cells. The consequences of this transdifferentiation of beta cells aren't yet clear but would be predicted to worsen insulin deficiency and raise blood glucose levels. More study is needed to understand how SARS-CoV-2 reaches the pancreas and what role the immune system might play in the resulting damage.



**COVID-19 Science Update:** On Friday, CDC [released their COVID-19 Science Update](#). This issue includes, but is not limited to, research on the following subjects: COVID-19 case investigation and contact tracing in the U.S. in 2020; emerging SARS-CoV-2 variants of concern evade humoral immune responses from infection and vaccination; and the indirect effect of mRNA-based COVID-19 vaccination on unvaccinated household members.

**NIH Study Offers New Evidence of Early COVID Infections in US:** NIH's [All of Us Research Program](#) found [evidence of SARS-CoV-2 infections in five states earlier than had initially been reported through new antibody testing](#). The findings suggest that SARS-CoV-2, the virus that causes COVID-19, was present in the U.S. as far back as December 2019. In the *All of Us* study, researchers analyzed more than 24,000 stored blood samples contributed by program participants across all 50 states between Jan. 2 and March 18, 2020. Researchers detected antibodies against SARS-CoV-2 using two different serology tests in nine participants' samples. The positive samples came as early as Jan. 7 from participants in Illinois, Massachusetts, Mississippi, Pennsylvania, and Wisconsin.

**COVID-19 Vaccination Coverage Among Pregnant Women During Pregnancy:** CDC released an *MMWR* on [COVID-19 vaccination coverage among pregnant women during pregnancy](#) in the United States from December 14, 2020 - May 8, 2021. Pregnant women are at increased risk for severe illness and death from COVID-19. As of May 8, 2021, 16.3% of pregnant women identified in CDC's Vaccine Safety Datalink had received  $\geq 1$  dose of a COVID-19 vaccine during pregnancy in the United States. Vaccination was lowest among Hispanic (11.9%) and non-Hispanic Black women (6.0%) and women aged 18–24 years (5.5%) and highest among non-Hispanic Asian women (24.7%) and women aged 35–49 years (22.7%). Improving outreach to and engagement with health care providers and pregnant women, especially those who are younger and from racial and ethnic minority groups, could increase vaccine confidence and thus coverage of COVID-19 vaccination in this population.

### **Other Resources**

[CDC Update for When You've Been Fully Vaccinated](#)

[CDC Updated Guidance for Safety Measures for Unvaccinated Individuals](#)

[CDC Public Health Recommendations](#)

[CDC Ensuring Equity in COVID-19 Vaccine Distribution](#)

[CDC Vaccinating Homebound Persons with COVID-19 Vaccine](#)

[CDC Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit](#)

[CDC Updated Guidance on Care for Breastfeeding People](#)

[CDC Updated Guidance on COVID-19 Vaccines While Pregnant or Breastfeeding](#)

[CDC Updated Guidance for Operating Child Care Programs During COVID-19](#)

[CDC Updated Guidance on Daily Activities and Going Out](#)

[CDC COVID-19 Employer Information for Gyms and Fitness Centers](#)

[CDC Updated Guidance for Businesses and Employers](#)

[CDC Updated Considerations for Restaurants and Bars](#)

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