



November 23, 2020

Dear Tribal and Urban Indian Organization Leaders:

There have been a lot of exciting developments these past couple of weeks. On Friday, Pfizer Inc. and BioNTech SE [submitted a request to the US Food and Drug Administration for Emergency Use Authorization \(EUA\) of their COVID-19 vaccine](#). And also last week, the National Institutes of Health announced that an independent data and safety monitoring board's interim review of data from [Moderna's investigational COVID-19 vaccine suggests that its vaccine is safe and highly effective](#).

As we get closer to a potential EUA for the COVID-19 vaccine, [FDA Commissioner Stephen Hahn reminded us](#) that these authorizations are an important tool in our country's fight against COVID-19 and other public health emergencies. The Commissioner's statement reaffirms FDA's commitment to transparency in the EUA process and shares some updates on our plan to provide more information about FDA's decisions to issue, revise or revoke these authorizations for drugs and biological products, including vaccines.

There are some exciting therapeutic and diagnostic developments as well. Effective therapeutics for COVID-19 are critically needed to treat patients who have been infected with COVID-19. Last week, FDA issued an [EUA](#) for the drug baricitinib, in combination with remdesivir, to treat suspected or laboratory confirmed COVID-19 in certain hospitalized patients requiring supplemental oxygen or ventilation.

The [FDA has also authorized the emergency use of Bamlanivimab](#) for the treatment of COVID-19. Bamlanivimab is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. The [IHS initially received 300 vials of Bamlanivimab](#). The IHS will use it to treat non-hospitalized patients with confirmed COVID-19 in areas of the country hardest hit by the pandemic. We are currently working with federal, tribal and urban Indian health program sites to assess capabilities for administration. The IHS [National Supply Service Center](#) will oversee allocation of the drug and coordinate its distribution in Indian Country.

And finally, FDA issued an [EUA](#) for Regeneron's investigational neutralizing antibodies casirivimab and imdevimab for the treatment of mild to moderate COVID-19 in non-hospitalized adults and pediatric patients 12 years and older, with a positive COVID-19 test, who are at high risk for progressing to severe COVID-19 and/or hospitalization.

At the Indian Health Service, we recently released our [IHS COVID-19 Pandemic Vaccine Plan November 2020](#). The plan details how the IHS health care system will prepare for and operationalize a vaccine when it becomes available. It also provides important guidance for all IHS federal, tribal health programs, and urban Indian organizations that choose to receive COVID-19 vaccine coordinated through IHS. The plan is the necessary groundwork for the distribution of a COVID-19 vaccine and ensures that safe and effective vaccines can reach Indian Country as quickly and equitably as possible.

Throughout this pandemic, the IHS has faced instances where it could not procure necessary goods through its ordinary sources of supply, and experienced a medical surge where access to care faced life-threatening circumstances. I am happy to share that last month, the Department of Veteran Affairs entered into an agreement with IHS that will assist our IHS federal facilities to access VA resources and services, such as staffing, acute care and Intensive Care Unit beds where appropriate and available during the pandemic. We established guidance and procedures for Federal staff to use on making requests and reimbursing VA under the agreement, as well as for services that VA provided since April 2020. For example, the VA will bill IHS for those services and supports by applying the VA Interagency Rates published in the [Federal Register](#). We are grateful for our partnership with the VA.

On December 8, from 1:00-4:00 pm ET, the Federal Emergency Management Agency will be conducting a virtual listening session to discuss coronavirus recovery policies and guidance and their implementation and impact on tribal nations. FEMA is interested in hearing feedback from tribal leaders on ways of improving the delivery of FEMA assistance and their experience during the COVID-19 Public Health Emergency. Please contact FEMA's Recovery Directorate by email at FEMA-Tribal-Recovery@fema.dhs.gov for more information.

On December 4, the [Administration for Children and Families Office of Child Support and Enforcement](#) will host a webinar entitled, [Managing Your Tribal IV-D Program During Difficult Times](#). The webinar will answer questions and provide feedback on how to handle the challenges of administering a child support program. From December 8-10, 2020, the ACF Office of Family Assistance will be convening both Department of Health and Human Services ACF Regions IX and X for a Virtual Tribal TANF Technical Assistance Meeting. The registration

link was shared with tribal TANF programs. The Office of Family Assistance will also host a virtual tribal TANF technical assistance meeting for Regions IV- VIII. Dates and details are forthcoming.

And as we approach this Thanksgiving holiday, please look at CDC's [Holiday Celebrations and Small Gatherings](#) page, as well as their page entitled [Know Your Travel Risk](#) to help you, your family, and your social circle make safe decisions.

Please stay safe and let us all continue to take responsible actions to stop the spread of COVID-19 and follow the three Ws: **Wear** a mask, **Wash** your hands, and **Watch** your distance.

I encourage you to visit our [IHS coronavirus webpage](#) for the latest information.

Respectfully,

Michael

RADM Michael D. Weahkee, MBA, MHSA
Assistant Surgeon General, U.S. Public Health Service
Director, Indian Health Service

Below is general information on various topics that could be of interest to you and your community. Web links are included where you can find more information on each topic.

Testing/Supplies/Diagnostics/Contact Tracing Resources:

Vaccine Research and Developments

- [FDA EUA COVID-19 diagnostic test for self-testing at home](#)
- [FDA FAQs on Testing for SARS-CoV-2](#)
- [CMS Guidelines for Holiday Visitation in Nursing Homes](#)
- [CDC Updated Information for Tribal communities](#)
- [CDC Updated Clinical FAQs](#)
- [CDC Updated Information for Workplaces and businesses](#)
- [CDC Updated Information for Community, work, and school](#)
- [CDC Guidance on Evaluating Community mitigation strategies](#)
- [CDC Updated Guidance on Community exposure to COVID-19](#)

- [CDC Guidance on Holiday gatherings](#)
- [CDC Social Media Toolkits for Holiday Gatherings done safely](#)
- [CDC Updated Considerations for Restaurants](#)
- [CDC One-Stop-Shop Toolkit on COVID-19](#)