

## FDA extends expiration date on Pfizer-BioNTech vaccine kept in ultra-low storage

The United States Food and Drug Administration (FDA) has approved an amendment to the EUA for Pfizer-BioNTech extending the expiration dates of COVID-19 vaccine from 6 to 9 months.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as authorized storage conditions between  $-90^{\circ}\text{C}$  to  $-60^{\circ}\text{C}$  ( $-130^{\circ}\text{F}$  to  $-76^{\circ}\text{F}$ ) have been maintained. Please note: the ultra-cold temperature range has been broadened to include  $-90^{\circ}\text{C}$  ( $-130^{\circ}\text{F}$ ). **Frozen vials stored at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$  and refrigerated vials ( $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ ) are NOT eligible for extension.**

Printed Expiry Date	Updated Expiry Date
August 2021	November 2021
September 2021	December 2021
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

Updated expiry dates for vaccine maintained in ultra-cold storage are shown below.

The extended expiration date is effective immediately for all currently available batches that have not yet expired. **NOTE:** Expiration dates extension does NOT apply to vials dated July 2021 and earlier.

No changes have been made to the vaccine itself to enable extension of expiry dating. This change is based on stability data generated on batches manufactured over approximately the past 9 months of COVID-19 vaccine development, from the batches that supplied early clinical trials through the commercial scale batches currently in production.

Currently available vaccine will not have an updated NCD. Please refer to the current EUA Fact Sheet for information.

Additional information on Pfizer storage and handling may be found at: Administration Overview for Pfizer-BioNTech COVID-19 Vaccine|CDC. ❖

## RI improves access to hepatitis C treatment for Medicaid patients

*State removes prior auth for two medications*

WASHINGTON, DC – The National Viral Hepatitis Roundtable (NVHR) and the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) applauded Rhode Island Medicaid for removing prior authorizations for two preferred treatments for hepatitis C, effective as of August 1, 2021. Rhode Island follows in the footsteps of just seven other states that do not require prior authorization for hepatitis C treatment, including California, Indiana, Louisiana, Michigan, New York, Washington, and Wisconsin. Nearly 23,000 Rhode Island residents are estimated to be living with hepatitis C. Removing prior authorizations will increase access to the hepatitis C cure for thousands of Medicaid beneficiaries living with hepatitis C.

“I applaud Rhode Island Medicaid for removing prior authorization processes for two hepatitis C regimens. It was a collective effort that got us to this point, and a decision made in response to ongoing work from healthcare workers, people with lived experience, and advocacy coming together,” said **LYNN E. TAYLOR, MD, FACP, FAASLD**, Director of HIV and Viral Hepatitis Services at CODAC Behavioral Health. “While this is a game-changing step forward towards hepatitis C elimination, we must continue to break down remaining barriers and discriminatory practices. Prior authorizations for direct-acting antivirals needed for patients with contraindications to the two Medicaid-preferred treatments remain in place, as do prior authorizations and high copay costs for individuals with commercial insurance.” Taylor’s organization, a non-profit based in Cranston, RI, provides outpatient treatment for Opioid Use Disorder across seven community-based locations and programming at the Rhode Island Department of Corrections.

“It is encouraging to see Rhode Island follow the lead of numerous other states to remove prior authorization requirements for hepatitis C treatments patients,” said **PHIL WATERS**, Staff Attorney at CHLPI. “We encourage all payors and providers to immediately implement the new policies to help improve public health outcomes, especially amid the ongoing coronavirus pandemic.”

The latest removal of prior authorizations for two preferred hepatitis C treatments has consequently increased Rhode Island’s Hepatitis C: State of Medicaid Access score to A+. ❖

## RIDOH launches Drug Overdose Surveillance Data Hub

With drug overdose deaths increasing both nationally and in Rhode Island, the Rhode Island Department of Health (RIDOH) has launched a new Rhode Island Drug Overdose Surveillance Data Hub to increase access to information about the overdose epidemic.

The Rhode Island Drug Overdose Data Hub was formally released in July during a meeting of Governor Dan McKee's Overdose Prevention and Intervention Task Force. The hub can be accessed at: [Health.ri.gov/od-datahub](https://health.ri.gov/od-datahub).

The hub has expanded public access to five overdose surveillance systems, and offers a closer look at detailed, municipal, county, and statewide trends. Featured surveillance systems include emergency department visits, emergency medical service runs, overdose fatalities from the RIDOH's Office of the State Medical Examiners and the State Unintentional Drug Overdose Reporting System, and prescribing data for the Rhode Island Prescription Drug Monitoring Program.

Community partners, researchers, students, and others can compare municipal-level data, such as age, sex, race, ethnicity, and incident/resident location, to county and statewide trends. People can also find municipal data reports, research publications, and request or download data.

"Rhode Island has long been a national leader in making drug overdose data accessible and available to the public. This new data hub provides an even more comprehensive resource and will be a critically important tool for harm reduction organizations, policy makers, researchers, and municipalities across the state," said **DR. BRANDON MARSHALL**, Development Team Lead for PreventOverdoseRI.org and Associate Professor of Epidemiology at Brown University School of Public Health.

The Rhode Island Drug Overdose Data Hub works together with PreventOverdoseRI.org to create a holistic view of how opioids and drug overdose are impacting the state. PreventOverdoseRI.org offers historical overdose data trends, interactive data stories, local resources, educational materials,

and campaigns. The dashboard also provides resources for people who may be at risk of overdose, healthcare providers who would like to learn more about treatment, as well as concerned loved ones. Since 2015, PreventOverdoseRI.org has been an online platform for real-time data to track the progress of the Governor's Overdose Prevention Action Plan.

RIDOH's new Data Hub links directly to PreventOverdoseRI.org to ensure data visualizations on both sites are updated automatically. Improvements in the data request process have been enhanced on the website, making it easier for the public to request data directly from RIDOH's Drug Overdose Surveillance Program.

"Data is knowledge, and knowledge is power. By providing accessible data and public resources, RIDOH is putting vital tools into the hands of outreach workers and community members to do life-saving work. We are grateful for the Department of Health's commitment to supporting overdose prevention and harm reduction efforts, including the Overdose Data Hub and PORI," said **ANNAJANE YOLKEN**, Director of Programs at Project Weber/RENEW.

Increasing public access to timely, accurate data has been a focus of the Rhode Island Executive Office of Health and Human Services (EOHHS) 2020 Evidence Update for the Governor's Overdose Prevention and Intervention Task Force.

Accidental drug overdose deaths increased by 25% from 2019 to 2020 (from 308 to 384). Preliminary 2021 fatal overdose data suggest that Rhode Island remains on a similar trajectory.

Rhode Islanders experiencing a substance use or mental health crisis can get connected to immediate care by calling the 24/7 BH Link Hotline, 401-414-LINK (5465) or visiting BH Link Walk-In Triage Center at 975 Waterman Avenue in East Providence.

The Data Hub adheres to RIDOH's Small Numbers Reporting Policy to ensure confidentiality. A tutorial about the Rhode Island Drug Overdose Data Hub is available online: <https://youtu.be/BPl7yk9mu58> ❖

## CODAC Behavioral Healthcare key partner in new smoking cessation effort

PROVIDENCE – CODAC Behavioral Healthcare is helping to lead a new statewide effort on tobacco cessation, especially among those in treatment for mental health and substance use disorders.

CODAC is uniquely positioned to contribute to the smoking cessation effort since it pioneered a dual substance use disorder and smoking cessation program in the early 2010s.

“CODAC has been really focused on tobacco cessation for 15 years. We were the first opioid treatment program in the country to become a tobacco-free campus. Tobacco is the only substance use disorder that will absolutely kill its users and is the leading cause of preventable deaths. Over fifty percent of the people who use tobacco will die of smoking-related conditions. However, because the fatalities are not as acute and because it’s legal, there continues to be this sense of diminished risk,” said **LINDA HURLEY**, President and CEO of CODAC.

In mid-July, 40 individuals representing tobacco control, behavioral health, public health, cancer control, primary providers, nonprofit organizations, and other services from across Rhode Island participated in a virtual summit hosted by SAMHA’s Tobacco Cessation Leadership Center.

Other sponsors of the summit included Rhode Island’s Department of Health, Rhode Island Department of Behavioral Healthcare, Developmental Disabilities and Hospitals, and the Executive Office of Health and Human Services.

Following the summit, four work groups have been established to identify existing resources and establish partnerships to effectively leverage these resources. The four groups are: Data, Education, Policy, and Systems Change, Equity, and Access. CODAC’s President and CEO Linda Hurley is co-chairing the Education subcommittee and CODAC’s Tobacco Program Coordinator, Carolyn James, is co-chairing the subcommittee on Systems Change, Equity, and Access.

Although smoking rates are on the decline nationally, a high number of adults and youth still smoke. In 2018, 14.6 percent of Rhode Island adults smoked and, in 2019, 4.2 percent of high school students had smoked cigarettes at least once in the past 30 days, according to CDC data. In addition, vaping has increased the popularity of tobacco use among youth. In 2019, 30.1 percent of high school students used electronic vapor products at least once in a 30-day period, according to the CDC. ❖

## Lifespan neurosurgeons perform incisionless thalamotomy

*MRI-guided focused ultrasound technology to treat patient tremors*

PROVIDENCE – Neurosurgeons at the Norman Prince Neurosciences Institute (NPNI) recently performed an incisionless thalamotomy using a novel image-guided focused ultrasound procedure to treat disabling tremors.

The procedure uses focused ultrasound energy guided by magnetic resonance imaging (MRI) to treat the brain circuit responsible for the patient’s tremors. The procedure is performed while the patient is awake so their response to treatment can be assessed in real time. It is for patients with essential tremor or tremor-dominant Parkinson’s disease whose tremors do not improve with medications.

During the procedure, MRI is used to target the precise location in the brain responsible for the tremor, and then an ultrasound helmet sends more than 1,000 beams of energy through the patient’s skull to thermally ablate the area without damaging surrounding brain tissue. After each application of energy the patient performs tasks such as drawing a spiral to allow evaluation of the tremor improvement during the treatment. At the end of the procedure a final MRI scan is done to assess the ablation area.

“Although Essential Tremor is relatively common and often fairly mild, there is a significant number of patients for whom the condition is more severe and debilitating, impairing a wide variety of routine daily activities such as eating, writing and getting dressed,” noted **Wael Asaad, MD, PhD**, director of the NPNI Functional Neurosurgery & Epilepsy program, and the neurosurgeon who performed the first procedure. “For those individuals who cannot find relief through medications, this procedure offers an effective, cutting-edge option without the cutting.”

It is usually performed as an outpatient procedure without sedation. The single session treatment takes about 2–3 hours to complete, and after a short recovery time patients can return home. ❖