LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 22-12: FDA Authorizes Second Booster Dose of Pfizer-BioNTech and the Moderna COVID-19 Vaccines for People 50 and Older or People 12 and Older with Moderate or Severe Immunosuppression**
Origination Date: *March 30, 2022*	**Revision Dates (List All Revision Dates):**

FDA authorizes a second booster dose of Pfizer-BioNTech and the Moderna COVID-19 vaccines for people 50 and older or people 12 and older with moderate or severe immunosuppression

The Food and Drug Administration (FDA) has authorized an additional (second) booster dose of the Pfizer-BioNTech and Moderna vaccines. This second booster dose is authorized for people 50 years of age and older, as well as individuals 12 years of age and older with moderate or severe immunosuppression. This second booster dose should be given at least 4 months after administration of one's first booster dose.

Moderately/severely immunosuppressed individuals aged 12-17 may receive a second booster of Pfizer vaccine while those aged 18 and up may receive either Pfizer or Moderna. Previously, immunocompromised individuals were eligible for an additional (third) mRNA primary series dose and one booster dose (4 total doses). Now, immunocompromised individuals 12 and up are eligible for a second booster, or fifth total dose.

This authorization offers additional protection to many vulnerable individuals from COVID-19, particularly in the event of a future surge.

- **Pfizer and Moderna Vaccines:** A second booster dose of both COVID-19 vaccines may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- **Pfizer Vaccine:** A second booster dose of the Pfizer-BioNTech COVID-19 vaccine may be administered to individuals 12 years of age and older with moderate or severe immunosuppression at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- **Moderna Vaccine:** A second booster dose of the Moderna COVID-19 vaccine may be administered to individuals 18 years of age and older with moderate or severe immunosuppression at least 4 months after the first booster dose of any authorized or approved COVID-19 vaccine.

Of note:

- Moderate/severe immunosuppression refers to solid organ transplant recipients or those with comparable levels of immunosuppression, such as cancer patients receiving chemotherapy, stem cell transplant patients taking immunosuppressive medicines, primary immunodeficiency such as DiGeorge syndrome and Wiskott-Aldrich syndrome,

advanced or untreated HIV infection, active treatment with high-dose corticosteroids or other immunosuppressive drugs, and other conditions or treatments.

- Pfizer booster doses are full-strength while Moderna booster doses are typically half the strength of Moderna primary series doses. Please pay close attention to vial packaging.

mRNA booster dose for Johnson & Johnson also approved
In addition, based on newly published data, adults who received a primary vaccine and booster dose of Johnson & Johnson's Janssen COVID-19 vaccine at least 4 months ago may now receive a second booster dose using an mRNA COVID-19 vaccine (Pfizer or Moderna)

Information to support authorization of a second COVID-19 booster dose
The FDA has determined the known and potential benefits of a second COVID-19 vaccine booster dose outweigh the known and potential risks in these populations. The evidence considered for authorization of a second booster dose following primary vaccination and a first booster dose included safety and immune response information provided to the agency as well as additional information on effectiveness submitted by the companies.
The guidance in this HAN is effective immediately.

Related Information
· CDC statement on FDA's authorization of second booster doses: https://www.cdc.gov/media/releases/2022/s0328-covid-19-boosters.html
· FDA Fact Sheets and other documents for Pfizer vaccine: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine
· FDA Fact Sheets and other documents for Moderna vaccine: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine
· COVID-19 Vaccine Overview: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
Emergency Use Authorization for Vaccines Explained: https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

LDH reminds providers to report possible vaccine-related adverse events to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

Any possible severe adverse events (those resulting in hospitalization, death, or persistent disability) should be immediately reported to the Office Public Health (OPH) Infectious Disease/Epidemiology Hotline at 1-800-256-2748.

If you have vaccine related questions, please contact la.immunization@la.gov

Any member of the public with questions on COVID-19 testing, therapeutics, vaccines, or other related issues can call the Louisiana COVID Community Hotline at 855-453-0774.