

Updated Guidance for COVID-19 Boosters for the Fall and Winter 2024–2025 Season

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Tallahassee, Fla. – The Florida Department of Health (Department) is reminding health care providers of the importance of remaining up to date with current literature related to COVID-19 vaccines and boosters, and the importance of providing patients with informed consent.

On [August 22, 2024](#), the United States Food and Drug Administration (FDA) approved and authorized updated versions of mRNA vaccines from Pfizer-BioNTech and Moderna. The FDA approved the vaccine for people 12 and older and provided emergency use authorization for children 6 months to 11 years old. The stated target of these boosters is the Omicron variant which is not causing a [significant number of infections](#).

The most recent booster [approval](#) was granted in the absence of booster-specific clinical trial data performed in humans. Furthermore, this booster does not protect against the currently [dominant strain](#), accounting for approximately 37% of infections in the United States. There are currently limited data to inform whether these boosters offer any substantial protection against the virus and subsequent [circulating variants](#). Although randomized clinical trials are normally used to approve therapeutics, the federal government has not required COVID-19 vaccine manufacturers to demonstrate their boosters prevent hospitalizations or death from COVID-19 illness.

Additionally, the federal government has failed to provide sufficient data to support the safety and efficacy of COVID-19 boosters, or acknowledge previously demonstrated safety concerns associated with COVID-19 vaccines and boosters, including:

- prolonged circulation of mRNA and spike protein in some vaccine recipients,

- increased risk of lower respiratory tract infections, and
- increased risk of autoimmune disease after vaccination.

Health care providers are encouraged to share information in this guidance in discussions with patients regarding the mRNA COVID-19 vaccines and boosters.

Based on the high rate of global immunity and currently available data, the State Surgeon General advises against the use of mRNA COVID-19 vaccines. Any provider concerned about the health risks associated with COVID-19 for patients over the age of 65 or with underlying health conditions should prioritize patient access to non-mRNA COVID-19 vaccines and treatment.

Safety and Efficacy Concerns

Providers and patients should be aware of outstanding mRNA COVID-19 vaccine safety and efficacy concerns:

- The mRNA COVID-19 vaccines present a risk of [subclinical](#) and clinical [myocarditis](#) and other cardiovascular conditions among otherwise healthy individuals.
- The mRNA COVID-19 vaccine may be associated with an increased risk of [postural orthostatic tachycardia syndrome](#) (POTS).
- The mRNA COVID-19 vaccine may be associated with an increased risk of [autoimmune diseases](#) including systemic lupus erythematosus (SLE), rheumatoid arthritis, and psoriasis.
- Throughout the pandemic, studies across geographic regions found that the mRNA COVID-19 vaccines are associated with [negative effectiveness](#) after four to six months. As efficacy waned, studies showed that COVID-19 vaccinated individuals developed an [increased risk](#) for infection.
- [Elevated levels](#) of mRNA and spike protein from the mRNA COVID-19 vaccine [persist](#) among some individuals for an indefinite period, which may carry [health risks](#).
- Potential [DNA integration](#) from the mRNA COVID-19 vaccines pose unique and elevated risk to human health and to the integrity of the human genome, including the risk that DNA

integrated into sperm or egg gametes could be passed onto offspring of mRNA COVID-19 vaccine recipients.

- There is unknown risk of potential adverse impacts with each additional dose of the mRNA COVID-19 vaccine; currently individuals may have received five to seven doses (and counting) of this vaccine over a 3-year period.

Improving habits and overall health help manage and reduce the risk of heart disease, type 2 diabetes, and obesity, risk factors for serious illness from COVID-19.

The State Surgeon General and the Department continue to encourage Floridians to prioritize their overall health by:

- Staying physically active,
- Minimizing processed foods,
- Prioritizing vegetables and healthy fats, and
- Spending time outdoors to support necessary vitamin D levels.

On September 13, 2023, State Surgeon General Dr. Joseph A. Ladapo provided [guidance](#) against COVID-19 boosters for individuals under 65 and younger. In addition to aforementioned concerns, providers and patients should be aware of outstanding safety and efficacy concerns outlined in the State Surgeon General's previous booster guidance released in September 2023.

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