

## **OPEN LETTER to Dr. Caitlin Newhouse, Medical Director, Vaccine-Preventable Diseases & Immunization Program, Tennessee Department of Health**

cc: Governor Bill Lee, Commissioner Dr. Ralph Alvarado, the General Assembly, TN Media Outlets

*RE: Your September 26, 2024 “Dear Colleague” Letter to TN Healthcare Providers*

Dear Dr. Newhouse:

In your September 26, 2024 TN Health Alert to Healthcare Providers<sup>1</sup>, you stated:

**“We encourage you to co-administer vaccines for eligible and interested patients, including RSV, COVID-19, and influenza.”**

Your recommendation includes babies as young as six months old and pregnant women. You link the Center for Disease Control & Prevention (CDC) web pages throughout your letter, but you fail to directly provide any evidence for the safety of your recommendation. The public’s trust in the CDC has been plummeting. In order for Tennesseans to be able to trust the healthcare providers who follow your advice, please provide the following in a publicly accessible “Dear Colleague” letter to all TN Healthcare Providers.

1. All clinical trials on which your claims of safety are based for the co-administering of RSV, COVID-19, and influenza products to babies, pregnant women, and others.
2. For each trial:
  - Whether or not the trial included enough participants to be considered sufficiently powered to reveal severe adverse reactions;
  - Whether or not the trial lasted long enough to inform about long-term safety issues;
  - The exclusion criteria and how those exclusions may impact trial results and whether the results can be generalized to the public.
3. A summary of types and numbers of adverse reactions reported to the Vaccine Adverse Event Reporting Systems (VAERS) and MedWatch for:
  - Individually administered RSV, COVID-19, and influenza products.
  - Co-administered RSV, COVID-19, and influenza products.
4. The states in the United States and the countries which no longer recommend COVID-19 vaccines for children, adolescents, young adults, pregnant women, or for anyone.
5. Guidance for reporting adverse reactions and filing for compensation for injuries or death due to co-administration when each product has a different legal liability status<sup>2</sup> for manufacturers and healthcare providers who administer them.

The public’s welfare is an urgent priority; please provide the requested information by November 1, 2024.

Sincerely,

Bernadette Pajer  
TN Director of Stand for Health Freedom

**STAND FOR**  
HEALTH FREEDOM

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<sup>1</sup> TNHAN+09.26.24+FINAL+Distributed-compressed.pdf (attached)

<sup>2</sup> <https://www.hrsa.gov/vaccine-compensation/covered-vaccines> ; RSV products not covered under VICP or CICIP.



# SEASONAL RESPIRATORY VIRUS VACCINES

## RESOURCE FOR PROVIDERS 2024-2025

Dear colleagues,

In recent respiratory virus seasons, Tennessee has ranked among the top states with high levels of infection, hospitalization, and mortality.

Your recommendations to patients regarding preventive products and vaccines are critical. The Tennessee Department of Health (TDH) appreciates your education of patients on the importance of immunization, hygiene, treatment, and isolation to prevent the spread of respiratory viruses. We encourage you to co-administer vaccines for eligible and interested patients, including RSV, COVID-19, and influenza. Please utilize the attached summary of available vaccines and preventive measures, Immunization Provider Toolkit and online resources to reduce the risk of respiratory viruses for your patients.

We appreciate your outstanding support for public health in Tennessee.



# RESPIRATORY SYNCYTIAL VIRUS (RSV)

Respiratory Syncytial Virus (RSV)

## **What products are available to prevent RSV infection?**

There are three options available to prevent severe RSV infection this 2024-2025 season:

1. Long-acting monoclonal antibody for infants and young children: Nirsevimab or Beyfortus™ (Sanofi)
2. RSVpreF vaccine for pregnant people to prevent severe disease in infants: RSVpreF or Abrysvo™ (Pfizer)
3. RSVpreF vaccines for older adults: RSVpreF or Abrysvo™ (Pfizer)/Arexvy™ (GSK)/mRESVIA™ (Moderna)

## **Who should receive these products?**

**Infants and young children** – CDC recommends 1 dose of Nirsevimab for:

1. Infants younger than eight months of age who were born shortly before or are entering their first RSV season (October through March) if:
  - The mother did not receive the RSV vaccine during pregnancy.
  - The mother's RSV vaccination status is unknown.
  - The infant was born within 14 days of maternal RSV vaccination.
  - Except in rare circumstances, Nirsevimab is not needed for most infants younger than age eight months who are born 14 or more days after their mother received the RSV vaccine.
- Some infants and children 8 through 19 months old are at increased risk for severe RSV disease and entering their second RSV season (typically October through March). \*

\*NOTE: Per CDC, typical RSV Season in the continental United States is October through March. Local epidemiology data in Tennessee supports RSV administration beginning in September for the 2024-2025 season.



**RSV**

**People who are 32–36 weeks pregnant:** CDC recommends a single dose of Pfizer bivalent RSVpreF vaccine (Abrysvo) for pregnant people between 32–36 weeks’ gestation to prevent severe RSV-associated lower respiratory tract disease in their infant(s). Vaccination should occur seasonally (September – January in most of the continental US). Most infants will not need to receive Nirsevimab if maternal RSV vaccination has occurred at least two weeks prior to delivery.

**Older adults:** CDC recommends a single dose of RSVpreF vaccine (either product) for all adults ages 75 years and older and for adults ages 60–74 years who are at increased risk of severe RSV, including individuals who:

- Have a chronic heart or lung disease
- Have a weakened immune system
- Have certain other medical conditions, including severe obesity and severe diabetes
- Live in a nursing home or other long-term care facility

***What are the benefits?***

Immunization against RSV can help prevent severe illness, hospitalization, and death for infants, toddlers, and older adults – groups who are most at-risk.

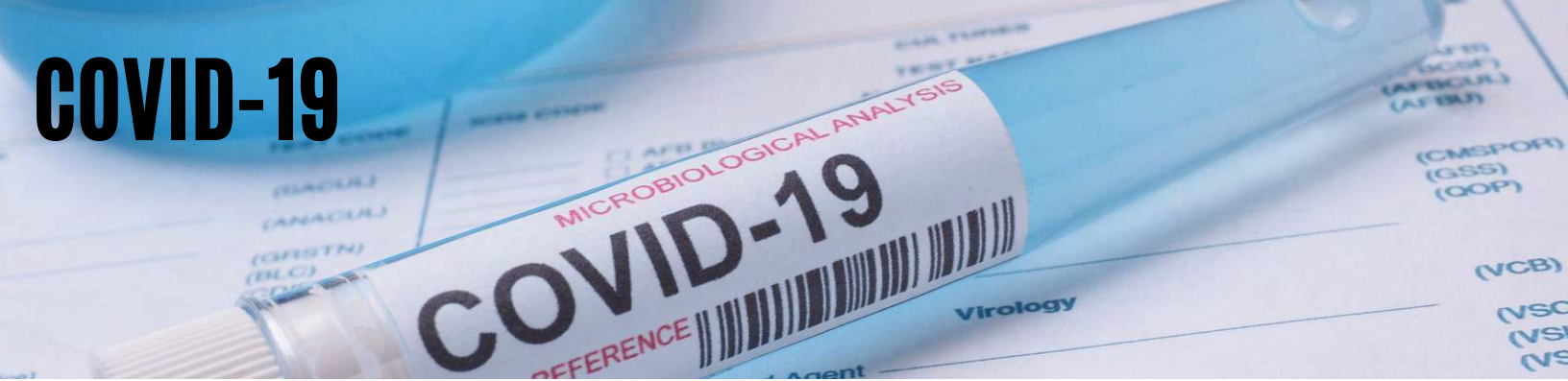
***Is RSV reportable to public health?***

Individual cases of RSV are not reportable in the state of Tennessee. However, RSV-associated death in a pediatric patient < 18 years of age is reportable in the state of Tennessee. Please see more information [here](#) regarding reporting requirements

***More information:***

- [RSV Vaccine Guidance for Older Adults](#)
- [RSV Immunizations to Protect Infants](#)

# COVID-19



## COVID-19

### ***What products are available to prevent COVID-19?***

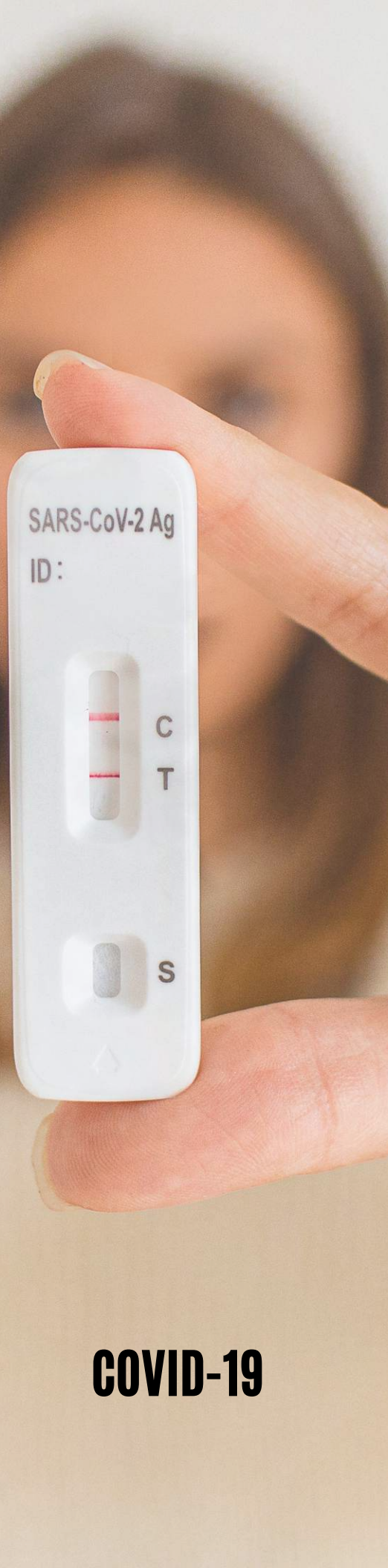
The updated 2024-2025 COVID-19 vaccines are available (Moderna, Pfizer-BioNTech, and Novavax). These vaccines are all monovalent (single strain) and based on the Omicron subvariants KP.2 (Pfizer and Moderna) and JN.1 (Novavax). With the authorization of the 2024-2025 formulations, the previous formulations are no longer authorized.

### ***Who should receive these products?***

According to the [CDC](#), everyone over 6 months of age is recommended to receive the 2024-2025 COVID-19 vaccine:

- Children 6 months to 4 years who were previously unvaccinated or have not completed a primary series are recommended to get 1-3 doses of the 2024-2025 COVID-19 mRNA vaccines (Pfizer or Moderna) to finish their primary series.
  - Children 6 months to 4 years who have received a primary series should receive 1 or 2 doses of 2024-2025 COVID-19 mRNA vaccines (Pfizer or Moderna) from the same manufacturer as administered for initial vaccination, depending on the vaccine and number of prior doses.
- Children 5-11 years are recommended to receive one dose of either 2024-2025 COVID-19 mRNA vaccines (Pfizer or Moderna) regardless of prior vaccination history.
- Children and adults 12 years and older should receive either one of the 2024-2025 mRNA COVID-19 vaccines (Pfizer or Moderna) or 2024-2025 Novavax COVID-19 vaccine depending on patient preference and dose history

For questions regarding specific scheduling scenarios, please refer to [Use of COVID-19 Vaccines in the United States \(CDC\)](#).



# COVID-19

## ***What are the benefits?***

COVID-19 vaccines are effective at protecting people from serious illness, hospitalization, and death from COVID-19; they also reduce the risk of Long COVID.

## ***What treatments are available?***

Treatment within 5-7 days of symptom onset (ideally <48 hours) with COVID-19 Treatments and Medications decreases risk of serious illness, hospitalization, and death. Healthcare providers are recommended to evaluate any symptomatic patient who tests positive for COVID-19 for treatment within 24 hours of seeking care to reduce the risk of hospitalization and death. Share this COVID-19 Medication Locator Tool with your patients so they can find a location to get COVID-19 testing or treatment nearby.

Antibody pre-exposure prophylaxis with Pemvibart (Pemgarda) is available for people who are moderately or severely immunocompromised ages 12 years and older. Pemvibart is given as an intravenous infusion over 60 minutes. If continued protection is needed, additional doses can be administered every 3 months. See more information here.

## ***Is COVID-19 reportable to public health?***

Positive COVID-19 test results are reportable from healthcare providers and laboratories. Visit the TDH COVID-19 webpage for information on reporting.

## ***What other resources are available?***

Four (4) free at-home COVID-19 tests are available for U.S. households through the federal government at COVIDTests.gov beginning October 1, 2024. Please use the following link to find local community-based COVID-19 testing sites via the Testing Locator Tool (select Tennessee in the state dropdown list).



## Influenza

### ***Which products are available to prevent influenza infection?***

Updated flu vaccines for 2024–2025 are available, including flu shots and a nasal spray flu vaccine. There are many flu vaccine options available this season, all are trivalent, meaning they protect against three strains of influenza virus. The three strains that are included in this season’s flu vaccines are influenza A(H1N1), A(H3N2) and B/Victoria-lineage. The influenza B/Yamagata vaccine component in this season’s flu vaccines has been removed because influenza B/Yamagata viruses have not been detected since March 2020.

Updated flu vaccines for 2024–2025 are available, including flu shots and a nasal spray flu vaccine. There are many flu vaccine options available this season, all are trivalent, meaning they protect against three strains of influenza virus. The three strains that are included in this season’s flu vaccines are influenza A(H1N1), A(H3N2) and B/Victoria-lineage. The influenza B/Yamagata vaccine component in this season’s flu vaccines has been removed because influenza B/Yamagata viruses have not been detected since March 2020?

Everyone aged six months and older should get an updated flu vaccine. People aged 65 and older should get a high-dose or adjuvanted flu vaccine if available.

### ***What are the benefits?***

Flu vaccines reduce the risk of flu illness, severe illness, hospitalization, and death. During seasons when flu vaccine viruses are similar to circulating flu viruses, flu vaccine has been shown to reduce the risk of having to go to the doctor with flu by 40 - 60%. Flu vaccines have been shown to reduce children’s risk of flu-related pediatric intensive care unit (PICU) admission by 74%. Flu vaccination among adults have been shown to reduce the risk of being admitted to an ICU with flu by 82%.

# INFLUENZA

## ***Where can I find a flu vaccine?***

Flu vaccine is widely available at pharmacies and many healthcare provider's offices. All Tennessee State Health Departments will offer free flu vaccines to the public for Fight Flu Tennessee Day on October 15, 2024. Visit TDH's [Fight Flu webpage](#) to find a Fight Flu Day Vaccine location, and its address and hours of operation. No appointment needed.

You can also visit [Vaccines.gov](#) to see where you can get a flu vaccine this year.

## ***What treatments are available?***

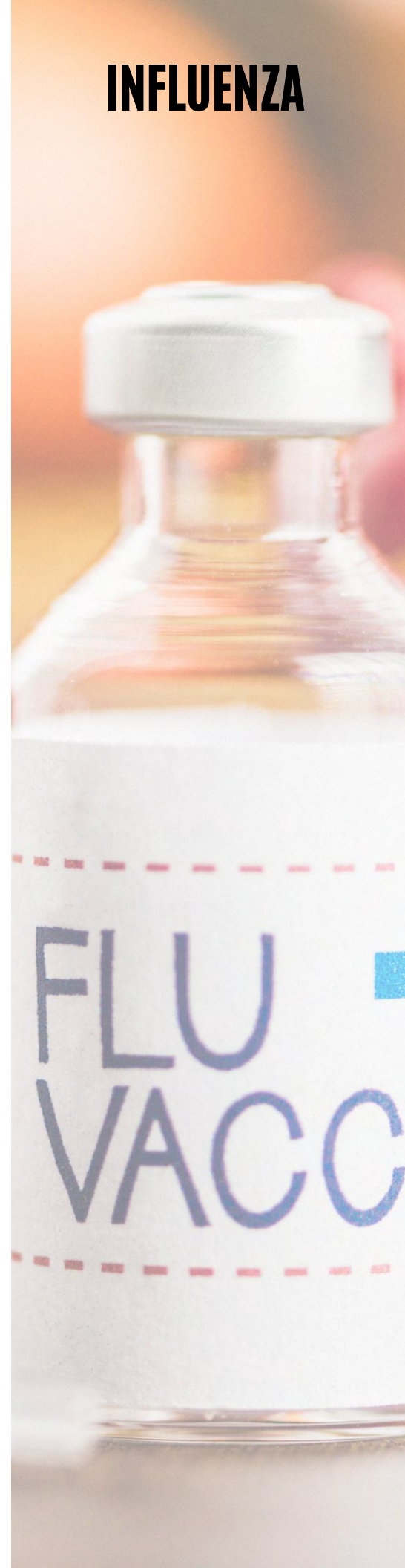
[Influenza antiviral treatment](#) is recommended as soon as possible (ideally <48 hours from symptom onset) for any patient with suspected or confirmed influenza who is hospitalized; has severe, complicated, or progressive illness; or is at higher risk for influenza complications.

## ***Is influenza reportable to public health?***

Individual cases of influenza are not reportable; however, sentinel surveillance partners in the state provide an overall picture of influenza activity through the Influenza-Like-Illness Surveillance Network (ILINet). Data from ILINet are published as weekly flu reports and can be found on [TDH's flu website](#).

In addition to ILINet, the following scenarios are reportable in Tennessee to enhance the understanding of the impact of influenza:

- Cases of novel influenza A (including H2, H5, H7, H9 subtypes)
  - Influenza-associated deaths among pregnant patients
  - Influenza-associated deaths among pediatric (<18yrs) patients
  - Influenza outbreaks (defined as 2 or more cases of laboratory-confirmed influenza identified within 72 hours of each other among individuals of a shared setting)





# AVIAN FLU H5N1

H5N1 PCR - Test

Reports can be faxed or emailed directly to the local or regional health office or to the Communicable and Environmental Diseases and Emergency Preparedness (CEDEP) Division at TDH.

### ***What should I know about Avian Flu (H5N1)?***

Be alert, but not alarmed! The risk of avian flu to the general public is currently low. Most human infections have been in people with direct contact to infected animals. Not all cases have reported respiratory symptoms; for some, conjunctivitis has been the only symptom. For patients presenting with influenza-like illness and/or conjunctivitis, consider H5N1 on the differential diagnosis and ask about exposure to birds, chickens, cows and pigs or consumption of raw milk or dairy products. If you have a symptomatic patient with a relevant exposure, call public health immediately (615) 532-8507 or (615)741-7247 or email [vpd.imm@tn.gov](mailto:vpd.imm@tn.gov)!

**More information:** [Prevent Seasonal Flu.](#)



## Recommendations

A clinician's recommendation is one of the most important factors in whether patients choose to accept a prevention product or vaccine. As we head into respiratory virus season this fall, it's important to understand new prevention tools, recommend them to patients who could benefit, and use them effectively to prevent severe respiratory disease. TDH encourages providers to:

1. Co-administer vaccines in the same visit, including RSV, COVID-19, and influenza vaccines for interested and eligible patients.
2. Consider testing patients with symptoms of acute respiratory illness and high-risk conditions for respiratory pathogens to inform patient management. Although treatment for RSV is supportive, diagnostic testing can help identify patients who might benefit from medications to treat other respiratory pathogens, such as COVID-19 and influenza. Real-time reverse transcription-polymerase chain reaction (rRT-PCR) is the preferred method for testing for respiratory viruses.
3. Educate healthcare personnel, childcare providers, and staff of long-term care facilities to stay home and not go to work when they have fever or symptoms of respiratory infection.

## For more information

- TDH Vaccine Preventable Diseases (VPD) Contact Information:
  - Toll Free: 800-404-3006
  - Fax: 615-741-3857
  - Email: [VPD.Imm@tn.gov](mailto:VPD.Imm@tn.gov)
- [TDH Reportable Diseases 2024](#)
- [TDH Respiratory Viral Illness](#)