

VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vi

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vi

1. Why get vaccinated?

Influenza vaccine can prevent influenza (flu).

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Live, attenuated influenza vaccine

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age may need 2 doses** during a single flu season. **Everyone else** needs only 1 dose each flu season.

Live, attenuated influenza vaccine (called "LAIV") is a nasal spray vaccine that may be given to non-pregnant people **2 through 49 years of age**.

It takes about 2 weeks for protection to develop after vaccination.

like diabetes, kidney or liver disorders, neurologic or neuromuscular or metabolic disorders)

- Does not have a spleen, or has a non-functioning spleen
- Has a cochlear implant
- Has a cerebrospinal fluid leak (a leak of the fluid that surrounds the brain to the nose, throat, ear, or some other location in the head)
- Has had Guillain-Barré Syndrome within 6 weeks after a previous dose of influenza vaccine

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

For some patients, a different type of influenza vaccine (inactivated or recombinant influenza vaccine) might be more appropriate than live, attenuated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Runny nose or nasal congestion, wheezing, and headache can happen after LAIV vaccination.
- Vomiting, muscle aches, fever, sore throat, and cough are other possible side effects.

If these problems occur, they usually begin soon after vaccination and are mild and short-lived.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/flu.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Vaccine Information Statement
Live, Attenuated Influenza Vaccine

42 U.S.C. § 300aa-26

8/6/2021

OFFICE
USE
ONLY





NOTICE OF PRIVACY PRACTICES

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION.

PLEASE REVIEW IT CAREFULLY

USES AND DISCLOSURES OF YOUR PROTECTED HEALTH INFORMATION

Protected health information includes demographic and medical information that concerns the past, present, or future physical or mental health of an individual. Demographic information could include your name, address, telephone number, Social Security number and any other means of identifying you as a specific person. Protected health information contains specific information that identifies a person or can be used to identify a person.

Protected health information is health information created or received by a health care provider, health plan, employer, or health care clearinghouse. The Department of Health (Department) can act as each of the above business types. This medical information is used by the Department in many ways while performing normal business activities.

Your protected health information may be used or disclosed by the Department for purposes of treatment, payment, and health care operations. Health care professionals use medical information in the clinics or hospital to take care of you. Your protected health information may be shared, with or without your consent, with another health care provider for purposes of your treatment. The Department may use or disclose your health information for case management and services. The Department clinic or hospital may send the medical information to insurance companies, Medicaid, or community agencies to pay for the services provided to you.

Your information may be used by certain Department personnel to improve the Department's health care operations. The Department also may send you appointment reminders, information about treatment options or other health-related benefits and services.

Some protected health information can be disclosed without your written authorization as allowed by law. These circumstances include:

- Reporting abuse of children, adults, or disabled persons.
- Investigations related to a missing child.
- Internal investigations and audits by the Department's divisions, bureaus, and offices.
- Investigations and audits by the state's Inspector General and Auditor General, and the Florida Legislature's Office of Program Policy Analysis and Government Accountability.
- Public health purposes, including vital statistics, disease reporting, public health surveillance, investigations, interventions, and regulation of health professionals.
- District medical examiner investigations.
- Research approved by the Department.
- Court orders, warrants, or subpoenas.
- Law enforcement purposes, administrative investigations, and judicial and administrative proceedings.

Other uses and disclosures of your protected health information by the Department will require your written authorization. These uses and disclosures may be for marketing or research purposes, certain uses and disclosure of psychotherapist notes, and the sale of protected health information resulting in compensation to the Department.

This authorization will have an expiration date that can be revoked by you in writing.

INDIVIDUAL RIGHTS

You have the right to request that the Department restrict the use and disclosure of your protected health information to carry out treatment, payment, or health care operations. You may also limit disclosures to individuals involved with your care. The Department is not required to agree to any restriction.

You have the right to be assured that your information will be kept confidential. The Department will contact you in the manner and at the address or phone number you select. You may be asked to put your request in writing. If you are responsible to pay for services, you may provide an address other than your residence where you can receive mail and where the department may contact you.

You have the right to inspect and receive a copy of your protected health information that is maintained by the Department within 30 days of the Department's receipt of your request to obtain a copy of your protected health information. You must complete the Department's Authorization to Disclose Confidential Information form and submit the request to the local county health department or Children's Medical Services office. If there are delays in the Department's ability to provide the information to you within 30 days, you will be told the reason for the delay and the anticipated date your request can be fulfilled.

Your inspection of the information will be supervised at an appointed time and place. You may be denied access to some records as specified by federal or state law.

If you choose to receive a copy of your protected health information, you have the right to receive the information in the form or format you request. If the Department cannot produce it in that form or format, you will be given the information in a readable hard copy form or another form or format that you and the department agree to.

The Department cannot give you access to psychotherapy notes or certain information being used in a legal proceeding. Records are maintained for specified periods of time in accordance with the law. If your request covers information beyond that time, the Department is not required to keep the record and the information may no longer be available.

If access is denied, you have the right to request a review by a licensed health care professional who was not involved in the decision to deny access. This licensed health care professional will be designated by the Department.

You have the right to correct your protected health information. A request to correct your protected health information must be in writing and provide a reason to support your requested correction.

The Department of Health may deny your request, in whole or part, if it limits the protected health information:

- Was not created by the Department.
- Is not protected health information.
- Is, by law, not available for your inspection.
- Is accurate and complete.

If your correction is accepted, the Department will make the correction and inform you and others who need to know about the correction. If your request is denied, you may send a letter detailing the reason you disagree with the decision. The Department may respond to your letter in writing. You also may file a complaint, as described below in the section titled Complaints.

You have the right to receive a summary of certain disclosures the Department may have made of your protected health information. This summary does not include:

- Disclosures made to you.

- Disclosures to individuals involved with your care.

- Disclosures authorized by you.
- Disclosures made to carry out treatment, payment, and health care operations.
- Disclosures for public health.
- Disclosures to health professional regulatory purposes.
- Disclosures to report abuse of children, adults, or disabled persons.
- Disclosures prior to April 14, 2003.

This summary does include disclosures made for:

- Purposes of research, other than those you authorized in writing.
- Responses to court orders, subpoenas, or warrants.

You may request a summary for not more than a 6-year period from the date of your request.

If you received this Notice of Privacy Practices electronically, you have the right to a paper copy upon request.

The Department of Health may send health care appointment reminders to you by postal mail, or by a telephone text or call.

PARTICIPATION IN THE HEALTH INFORMATION EXCHANGE NETWORK

Access to information about your health history and medical care is critical to help ensure that you receive high-quality care and gives your health care provider a more complete picture of your overall health. This can help your provider make informed decisions about your care. The information may also prevent you from having repeat tests, saving you time, money, and worry. Recent advancements in technology now support the safe and secure electronic exchange of important clinical information from one health care provider to another through Health Information Exchange (HIE) networks. The Department and its county health departments participate in an HIE network and also participate in several HIE networks with trusted outside health care providers to quickly and securely share your health information electronically among a network of health care providers, including physicians, hospitals, laboratories and pharmacies. Your health information is transmitted securely and only authorized health care providers with a valid reason may access your information. By sharing information electronically through a secure system, the risk that your paper of faxed records may be misused or misplaced is reduced.

Participation in HIE is completely your choice.

Choice 1. YES to HIE participation. If you agree to have your medical information shared through HIE and you have a current Initiation of Services form on file, you need not do anything. By signing that form, you have granted the Department permission to share your health information through the HIE.

Choice 2. NO to HIE participation. You can choose to not have your information shared electronically through the HIE network (opt out) at any time, by completing the Health Information Exchange Opt-Out Form available at the county health department. If you decide to opt out of HIE, health care providers will not be able to access your health information through HIE. You should understand that if you opt out, the health care providers treating you are still permitted to contact the Department to ask that your health information be shared with them as stated in this Notice of Privacy Practices. Opting out does not prevent information from being shared between members of your care team. Please note, opting out does not affect health information that was disclosed through HIE prior to the time you opted out.

Choice 3: You can change your mind at any time

You may consent today to the sharing of your information via HIE and change your mind later by following the instructions on the opt out form described under Choice 2.

Alternatively, you may opt out of HIE today and change your mind later by submitting the Department's Revocation of HIE Opt-Out Request Form.

PERSONAL HEALTH RECORDS (PHR) MOBILE APPLICATION

SYNCHRONIZATION WITH USER DATA

As part of the services provided by the Department, you can download the companion PHR mobile application to access your personal health records. This application is the mobile version of the Florida Health Connect portal.

The purpose of the PHR mobile application is to provide you with access to your health information through your mobile device. You can synchronize your Florida Health Connect account through the mobile application with your personal health information captured on your mobile device (Google Fit or Apple Health) to provide you with a 360-degree view of your health history and current health status.

Your Google Fit or Apple Health information will not be disclosed to any third parties without your express written permission.

DEPARTMENT OF HEALTH DUTIES

The Department is required by law to maintain the privacy of your protected health information. This Notice of Privacy Practices tells you how your protected health information may be used and how the Department keeps your information private and confidential. This notice explains the legal duties and practices relating to your protected health information. The Department has the responsibility to notify you following a breach of your unsecured protected health information.

As part of the Department's legal duties, this Notice of Privacy Practices must be given to you. The Department is required to follow the terms of the Notice of Privacy Practices currently in effect.

The Department may change the terms of its notice. The change, if made, will be effective for all protected health information maintained by the Department. New or revised Notices of Privacy Practices and all forms referenced in this Notice of Privacy Practices may be accessed on the Department's website at <http://www.floridahhs.gov/about/office-of-public-affairs/health-information> and will be available by email and at all Department of Health locations. Also available are additional documents that further explain your rights to inspect, copy, or amend your protected health information.

COMPLAINTS

If you believe your privacy health rights have been violated, you may file a complaint with the Department of Health's Inspector General at 4052 Bald Cypress Way, BIN A03 Tallahassee, FL 32399-1704 (telephone 850-246-4141 and with the Secretary of the U.S. Department of Health and Human Services at 200 Independence Avenue, S.W./ Washington, D.C. 20201/ telephone 202-619-0257 or toll free 877-696-6775.

The complaint must be in writing, describe the acts or omissions that you believe violate your privacy rights, and be filed within 180 days of when you knew or should have known that the act or omission occurred. The Department will not retaliate against you for filing a complaint.

FOR FURTHER INFORMATION

Requests for further information about the matters covered by this notice may be directed to the person who gave you the notice, to the director or administrator of the Department of Health facility where you received the notice, or to the Department of Health's Inspector General at 4052 Bald Cypress Way, BIN A03 Tallahassee, FL 32399-1704 (telephone 850-246-4141).

EFFECTIVE DATE

This Notice of Privacy Practices is effective beginning February 21, 2022, and shall remain in effect until a new Notice of Privacy Practices is approved and posted.

REFERENCES

- Standards for the Privacy of Individually Identifiable Health Information: Final Rule, 49 CFR Parts 160 through 164, Federal Register 65, no. 239 (December 26, 2009).
- Standards for the Privacy of Individually Identifiable Health Information: Final Rule 45 CFR Part 160 through 164, Federal Register, Volume 87 (August 14, 2002).
- HHS, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information and Nondiscrimination Act: Other Modifications to the HIPAA Rules, 78 Fed. Reg. 56565 (Jan. 25, 2013).

