

VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

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

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

Flu vaccine can:

- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

2 Inactivated and recombinant flu vaccines

A dose of flu vaccine is recommended every flu season. Children 6 months through 8 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have not shown thimerosal in vaccines to be harmful, but flu vaccines that do not contain thimerosal are available.

There is no live flu virus in flu shots. **They cannot cause the flu.**

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three or four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn’t exactly match these viruses, it may still provide some protection.

Flu vaccine cannot prevent:

- flu that is caused by a virus not covered by the vaccine, or
- illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.

3 Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.**
If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.
- **If you ever had Guillain-Barré Syndrome (also called GBS).**
Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
- **If you are not feeling well.**
It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to come back when you feel better.



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

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get a flu shot do not have any problems with it.

Minor problems following a flu shot include:

- soreness, redness, or swelling where the shot was given
- hoarseness
- sore, red or itchy eyes
- cough
- fever
- aches
- headache
- itching
- fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

More serious problems following a flu shot can include the following:

- There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated flu vaccine. This risk has been estimated at 1 or 2 additional cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.
- Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get the person to the nearest hospital. Otherwise, call your doctor.
- Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does 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.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- 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

Vaccine Information Statement
Inactivated Influenza Vaccine

08/07/2015

42 U.S.C. § 300aa-26

Office Use Only





**Texas Department of State Health Services
Addendum to Inactivated Influenza Vaccine
Vaccine Information Statement**

1. I agree that the person named below will get the vaccine checked below.
2. I received or was offered a copy of the Vaccine Information Statement (VIS) for the vaccine listed above.
3. I know the risks of the disease this vaccine prevents.
4. I know the benefits and risks of the vaccine.
5. I have had a chance to ask questions about the disease the vaccine prevents, the vaccine, and how the vaccine is given.
6. I know that the person named below will have the vaccine put in his/her body to prevent the disease this vaccine prevents.
7. I am an adult who can legally consent for the person named below to get the vaccine. I freely and voluntarily give my signed permission for this vaccine.

Vaccine to be given: Inactivated Influenza Vaccine

***STATEMENT: I authorize the release of any medical or other information necessary to process the claim. I also request payment of government benefits to the party who accepts assignment.**

Provider Identification Number: _____ **Aurora Concepts, LLC**

Medicare Health Insurance Claim Number: _____ 233 Hurst Street, Suite B
Center, Texas 75935

| Information about person to receive vaccine (Please print) | | | | | | Office: 936-598-3206 Fax: 936-598-9208 | |
|--|-------|----------------|-------------------------|---------------------|--|--|--|
| Name: Last | First | Middle Initial | Birthdate (mm/dd/yy) | Sex (circle one) | | | |
| | | | | M F | | Date Vaccine Administered: | |
| Address: Street | City | County | State | Zip | | | |
| | | | | TX | | Vaccine Manufacturer: | |
| Signature of person to receive vaccine or person authorized to make the request (parent or guardian): X _____ Date _____ X _____ Date _____ Witness | | | | | | Vaccine Lot Number: | |
| | | | | | | Site of Injection: | |
| | | | | | | Signature of Vaccine Administrator: | |
| | | | | | | Title of Vaccine Administrator: | |

PRIVACY NOTIFICATION - With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003, and 559.004)

Privacy Notice: I acknowledge that I have received a copy of my immunization provider's HIPAA Privacy Notice.

Notice: Alterations or changes to this publication is prohibited without the express written consent of the Texas Department of State Health Services, Immunization Branch.

Instructions: File this consent statement in the patient's chart.

