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Purpose of this Guide

The purpose of this guide is for general educational purposes only. Please discuss individual patient conditions with the patient’s physician(s) prior to administration of any vaccine or pharmaceutical. Also refer to the product package insert for the full prescribing information of any vaccine or pharmaceutical listed.

Acknowledgements

The majority of the information provided here is available publicly through various government websites that are referenced throughout this guide. Primarily, the Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services (HHS), the Immunization Action Coalition, and the Centers for Medicaid and Medicare Services (CMS) were instrumental in our information gathering. The nature of drug information is that it is constantly evolving because of ongoing research and clinical experience and is often subject to interpretation. While great care has been taken to ensure the accuracy of the information presented, the reader is advised that the authors, editors, reviewers, contributors and publishers cannot be responsible for the continued currency of the information. All readers are advised that decisions regarding drug therapy and treatment must be based on the independent judgment of treating clinicians, changing information about a drug (e.g., as reflected in literature and the manufacturer’s most current product information), and changing medical practices. The editors are not responsible for any inaccuracy of quotations or for any false or misleading implication that may arise due to the text or formulas as used or due to the quotation of revisions no longer official. PharMerica Corporation does not represent or warrant the accuracy of the information provided in this manual and nothing in this manual is intended to replace the treatment by an established clinician. No official support or endorsement by any federal or state agency or pharmaceutical company is intended or inferred.
CMS Requires Flu/Pneumococcal Vaccinations for Nursing Homes

The Centers for Medicare and Medicaid Services (CMS) requires nursing facilities participating in the Medicare and Medicaid programs to offer all residents influenza and pneumococcal vaccines and document the results. According to the requirements, each resident is to be vaccinated unless contraindicated medically, the resident or a legal representative refuses vaccination, or the vaccine is not available because of shortage.

This information is to be reported in Section O of the CMS Minimum Data Set (MDS 3.0), which tracks nursing home health parameters. CMS uses this data in the Nursing Home Star Rating Program, measuring the percent of both short-stay and long-stay residents assessed and given, appropriately, the seasonal influenza vaccine and the pneumococcal vaccine.

Surveyors will assess each facility’s vaccination policies and procedures for compliance during the annual survey. The full content of F-tag 883 can be viewed at:


The use of standing orders by nursing homes and skilled nursing facilities, hospitals, and home health agencies ensures that vaccination is offered.

Generally, a standing orders program for influenza vaccinations would be conducted under the supervision of a licensed practitioner according to a physician-approved facility or agency policy by a Health Care Professional (HCP) trained to screen patients for contraindications to vaccination, administer vaccines, and monitor for adverse events. However, CMS has removed the physician signature requirement for the administration of influenza and pneumococcal vaccines to Medicare and Medicaid patients in hospitals, long-term care facilities, and home health agencies. To the extent allowed by local and state law, these facilities and agencies may implement standing orders for influenza and pneumococcal vaccination of Medicare- and Medicaid-eligible patients.

In its collaborative effort to improve quality of care, CMS is also encouraging nursing facilities to provide the influenza vaccine to their healthcare workers. Immunizing nursing staff has been shown to reduce mortality rates among residents of long-term care facilities.
## Medicare Coverage of Vaccinations

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Primary Updates and Notifications in the 2018-19 Recommendations

• For the 2018-19 season, quadrivalent and trivalent influenza vaccines will be available. Inactivated influenza vaccines (IIVs) will be available in trivalent (IIV3) and quadrivalent (IIV4) formulations. Recombinant influenza vaccines (RIV) and live attenuated influenza vaccines (IIV4) are also available. High-dose inactivated vaccines (HD-IIV3) and adjuvanted inactivated influenza vaccines (aIIV3) will be available in trivalent formulations.

• ACIP has determined that LAIV4 is an option for those in whom it is appropriate following two seasons (2016-17 and 2017-18) in which ACIP previously recommended that LAIV4 not be used. FluMist® Quadrivalent, the U.S. brand name of LAIV4, is indicated for utilization in patients 2-49 years of age. LAIV4 is NOT indicated for patients >50 years.

  - LAIV was effective against influenza B viruses, and effectiveness of LAIV and IIV against influenza A (H3N2) viruses generally did not differ significantly.

• For persons aged >65, any age-appropriate IIV formulation (standard dose or high dose, trivalent or quadrivalent, unadjuvanted or adjuvanted) is recommended.

  - No preferential recommendation is made for any specific vaccine product when more than one licensed, recommended, and appropriate product is available. Vaccination should not be delayed if a specific product is not readily available.

  - Data from studies comparing the efficacy or effectiveness of HD-IIV3 (Fluzone High-Dose), aIIV3 (Fluad), and unadjuvanted SD-IIV3 (Afluria, etc) with one another against laboratory-confirmed influenza outcomes among older adults are limited, which prevents recommending one of these three vaccines over another for this population.

  - Fluzone® High-Dose met prespecified criteria for superior efficacy to that of SD-IIV3 in a randomized trial conducted over two seasons among 31,989 persons aged >65, and might provide better protection than SD-IIV3 for this age group.

  - Flublok® Quadrivalent was more efficacious than SD-IIV4 in an exploratory analysis of data from a single-season randomized trial conducted among 8,604 adults aged > 50 years; however, no claim of superiority was approved for the package insert.

  - Fluad® was more effective against laboratory-confirmed influenza than unadjuvanted SD-IIV3 among adults aged >65 in an analysis from a small observation study.
• All of the 2018-19 U.S.-licensed influenza vaccines will contain the following three strains: an A/Michigan/45/2015 (H1N1)pdm09-like virus, an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus, and a B/Colorado/06/2017-like virus (Victoria lineage).

• Four-component (quadrivalent) vaccines, which protect against a second lineage of B viruses, are recommended to be produced using the same viruses recommended for the trivalent vaccines, as well as a B/Phuket/3073/2013-like virus (Yamagata lineage).

• **Persons with a history of egg allergy of any sensitivity may receive any licensed, recommended, and age-appropriate influenza vaccine (IIV, RIV4, or LAIV4).**
  - Persons with a history of reactions to egg who experience only urticarial (hives) should receive one of any licensed, recommended, and age-appropriate influenza vaccines (e.g., any IIV, RIV4, or LAIV4) that is otherwise appropriate.
  - Persons with a history of reactions to egg involving other than urticarial (hives), such as angioedema, respiratory distress, lightheadedness, or recurrent emesis, or who required epinephrine or other emergency medical intervention, may similarly receive any licensed, recommended, and age-appropriate influenza vaccine (e.g., any IIV, RIV4, or LAIV4) that is otherwise appropriate.
  - RIV4 (Flublok Quadrivalent) is the only egg-free influenza vaccine available; cclV4 (Flucelvax Quadrivalent) egg ovalbumin is not directly measured, but egg is not used in the manufacturing process, resulting in a theoretical maximum of 1.7x10^-8µg/0.5ml.
Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know

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.

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.

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.
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/](http://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 website at [www.vaers.hhs.gov](http://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](tel:1-800-338-2382) or visiting the VICP website at [www.hrsa.gov/vaccinecompensation](http://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](tel:1-800-232-4636) ([1-800-CDC-INFO](tel:1-800-CDC-INFO)) or
  - Visit CDC’s website at [www.cdc.gov/flu](http://www.cdc.gov/flu)

Vaccine Information Statement

Inactivated Influenza Vaccine

[08/07/2015]

42 U.S.C. § 300aa-26
Consent for Flu and Pneumococcal Vaccines

Resident: ___________________________  Birth Date: ___________________________

ID Number: ___________________________  Nursing Care Center: ___________________________

Living Unit: ___________________________  Physician: ___________________________

INFORMATION:

It is not possible to estimate the risk of an individual getting the flu this year, but for the elderly and for people with diabetes or heart, lung or kidney diseases, the flu may be especially serious. An injection of the flu vaccine will not give you the flu because the vaccine is made from killed viruses. The vaccine is made from viruses selected by the Office of Biologics, Food and Drug Administration, and the Public Health Service. Side effects of the influenza vaccine are generally mild in adults and occur at low frequency. These reactions consist of tenderness at the injection site, fever, chills, headaches, or muscular aches. These symptoms can last up to 48 hours.

Guillain-Barré Syndrome (GBS) is typically characterized by a paralysis that begins in the hands or feet and then moves up the arms or legs or both. GBS is usually self-limiting, and most persons with GBS recover without permanent weakness. In approximately five percent of the cases, a permanent or even fatal form of paralysis may occur. In 1976, GBS appeared with excess frequency among persons who had received the 1976 swine flu vaccine. For the ten weeks following vaccination, the risk of GBS was found to be approximately ten cases for every one million persons vaccinated. This represented a five- to six-times higher risk than in unvaccinated persons.

Data on the occurrence of GBS have been collected during three influenza seasons since the surveillance began in 1978. These data suggests that, in contrast to the 1976 situation, the risk of GBS in recipients of the influenza vaccine was not significantly higher than that in those not vaccinated. Nonetheless, persons who receive influenza vaccines should be aware of this possible risk compared to the risk of influenza and its complications.

SPECIAL PRECAUTIONS:

• Consult with a prescriber for use in children under three years of age and pregnant women.
• Persons who are allergic to eggs, chicken feather, or chicken dander should not receive this vaccine until they have consulted their prescriber.
• Persons who are allergic to eggs, latex, or thimerosal should not receive this vaccine until they have consulted their prescriber.
• Persons with a fever should not receive this vaccine. Persons who have received another type of vaccine within the past fourteen days should see their prescriber before receiving this vaccine.
• If you have a reaction, see your prescriber immediately. If you have any questions, please ask.

Has the person receiving the vaccine ever had a severe allergic (hypersensitivity) reaction to eggs, latex, or thimerosal? ❑ YES ❑ NO

*Specify____________________

Does the person receiving the vaccine have a history of Guillain-Barré syndrome or a persistent neurological illness? ❑ YES ❑ NO

Has the person received a live vaccine within the past 30 days (i.e. MMR, Rotarix, Zostavax) ❑ YES ❑ NO

*If YES, recommended to spacing live vaccines by >4 weeks for full efficacy

Is the person receiving the vaccine currently sick with a fever? ❑ YES ❑ NO

Is the person receiving the vaccine currently receiving radiation, chemotherapy, or immunosuppressive therapy? ❑ YES ❑ NO

I have read the above information and VIS for my requested vaccination and have had an opportunity to ask questions. I understand the benefits and risks of flu and pneumonia vaccinations as described. I request that the vaccine be given to me or to the person named below for whom I am authorized to sign.

❑ Influenza   ❑ PPSV23 (Pneumovax)   ❑ PCV13 (Prevnar)

Resident Name (please print) ___________________________  Date of Birth: ___________________________

Age ___________________________

Address ___________________________

City ___________________________

State ___________________________

Zip Code ___________________________

X ___________________________

Signature of person to receive vaccine (or authorized guardian)

----------------------------------- FOR OFFICE USE ONLY -----------------------------------

Date/Time of Administration: ___________________________

Lot #: ___________________________

Immunizer: ___________________________

Expiration Date: ___________________________

Vaccine Name: ___________________________

❑ Right arm   ❑ Left arm   ❑ Other: ____________
Declination of Influenza or Pneumococcal Vaccination

My health facility, _________________________, has recommended that I receive an influenza and/or pneumococcal vaccination to protect myself and other residents or employees in the facility.

I acknowledge that I am aware of the following facts:

**Influenza**

- Influenza is a serious respiratory disease that kills thousands of people in the U.S. each year.
- Influenza vaccination is recommended for me to protect this facility’s patients from influenza, its complications, and death.
- If I contract influenza, I can shed the virus for 24 hours before influenza symptoms appear.
- My shedding of the virus can spread influenza to patients in this facility.
- If I become infected with influenza, even if my symptoms are mild or non-existent, I can spread it to others and they can become seriously ill.
- I understand that I cannot get influenza from the influenza vaccine.
- The consequences of my refusing to be vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact.
- Influenza vaccination is recommended by the Centers for Disease Control and Prevention.

**Pneumococcal**

- Pneumococcal disease kills more people in the U.S. each year than all other vaccine-preventable diseases combined.
- Those >65 years, the very young, and people with special health problems (alcoholism, heart or lung disease, kidney failure, HIV, certain cancers) are at greater risk.
- Pneumococcal disease can lead to serious infections of the lungs (pneumonia), the blood (bacteremia), and the covering of the brain (meningitis).
- The bacteria causing pneumococcal disease have become more resistant to antibiotics used today, making prevention even more important.
- Pneumococcal vaccination is recommended by the Centers for Disease Control and Prevention.

I was offered a vaccination of (please circle): **Influenza Vaccine**  **Prevnar13**  **Pneumovax23**

Despite these facts, I am choosing to decline vaccination right now for the following reasons:

________________________________________________________________________________________
________________________________________________________________________________________

I understand that I can change my mind at any time and accept this vaccination if it is still available.

I have read and fully understand the information on this declination form.

Signature:_________________________          Date:_____________

Name (print):_________________________

Developed using references published by the Immunization Action Coalition at www.immunize.org.
Influenza Adult Immunization Guide | 2018-2019

Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities

The following guidance is current for the 2016-2017 influenza season. Please see Recommendations of the Advisory Committee on Immunization Practices – United States, 2016-17 Season for the latest information regarding recommended influenza vaccines. Please see Antiviral Drugs: Information for Health Care Professionals for the current summary of recommendations for clinical practice regarding the use of influenza antiviral medications.

Long-term care facilities may be defined as institutions, such as nursing homes and skilled nursing facilities that provide health care to people (including children) who are unable to manage independently in the community. This care may represent custodial or chronic care management or short-term rehabilitative services.

Influenza can be introduced into a long-term care facility by newly admitted residents, health care workers and by visitors. Spread of influenza can occur between and among residents, health care providers, and visitors. Residents of long-term care facilities can experience severe and fatal illness during influenza outbreaks.

Preventing transmission of influenza viruses and other infectious agents within health care settings, including in long-term care facilities, requires a multi-faceted approach that includes the following:

• Vaccination
• Testing
• Infection Control
• Antiviral Treatment
• Antiviral Chemoprophylaxis

Before an Outbreak Occurs

Influenza vaccination should be provided routinely to all residents and health care workers of long-term care facilities.

Residents

If possible, all residents should receive trivalent inactivated influenza vaccine (TIV) annually before influenza season. In the majority of seasons, TIV will become available to long-term care facilities beginning in September, and influenza vaccination should commence as soon as vaccine is available. Informed consent is required to implement a standing order for vaccination, but this does not necessarily mean a signed consent must be present.

In the event that a new patient or resident is admitted after the influenza vaccination program has concluded in the facility, the benefits of vaccination should be discussed, educational materials should be provided, and an opportunity for vaccination should be offered to the new resident as soon as possible after admission to the facility. Since October 2005, the Centers for Medicare and Medicaid Services (CMS) has required nursing homes participating in Medicare and Medicaid programs to offer all residents influenza and pneumococcal vaccines and to document the results. According to requirements, each resident is to be vaccinated unless contraindicated medically, the resident or legal representative refuses vaccination, or the vaccine is not available because of storage. This information is to be reported as part of the CMS Minimum Data Set, which tracks nursing home health parameters.

Health Care Personnel

CDC and the Advisory Committee on Immunization Practices (ACIP), recommend that all U.S. health care personnel get vaccinated annually against influenza.

• Health care personnel who get vaccinated help to reduce the following:
  • Transmission of influenza
  • Staff illness and absenteeism
  • Influenza-related illness and death, especially among people at increased risk for severe influenza illness
  • Higher vaccination levels among personnel have been associated with a lower risk of health care facility-associated influenza cases.
  • Influenza outbreaks in hospitals and long-term care facilities have been attributed to low influenza vaccination coverage among health care personnel.
  • Higher influenza vaccination levels among health care personnel can reduce influenza-related illness, and even deaths, in settings like nursing homes.
Surveillance

When there is influenza activity in the local community, active daily surveillance (defined below) for influenza illness should be conducted among all new and current residents, staff, and visitors of long-term care facilities, and continued until the end of influenza season. Ill residents, personnel, and visitors should be excluded from the facility until illness has resolved.

Testing

Even if it’s not influenza season, influenza testing should occur when any resident has signs and symptoms of influenza-like illness. More information about testing is included below.

When there is a confirmed or suspected influenza outbreak (2 or more ill residents)

If there is one laboratory-confirmed influenza positive case along with other cases of respiratory infection in a unit of a long-term care facility, an influenza outbreak might be occurring.

While unusual, an influenza outbreak can occur outside of the normal influenza season; therefore, testing for influenza should be added to testing for other respiratory pathogens during non-influenza season periods.

Even if it’s not influenza season, influenza testing should occur when any resident has signs and symptoms that could be due to influenza *, and especially when two residents or more develop respiratory illness within 72 hours of each other.

- Determine if influenza virus is the causative agent by performing influenza testing on respiratory specimens (i.e. nasal swabs, throat swabs, nasopharyngeal swab, or nasopharyngeal or nasal aspirates) of ill residents with recent onset of signs and symptoms suggestive of influenza.
- In order of priority, the following influenza tests are recommended: reverse transcription polymerase chain reaction (RT-PCR); immunofluorescence; rapid influenza diagnostic tests.
- Because of the possibility of false negative results during influenza season, if influenza is suspected and immunofluorescence or rapid influenza diagnostic test results are negative, perform confirmatory testing using RT-PCR or viral culture. Information on influenza diagnostic testing is available online or by contacting your state public health laboratory.
- Because of the possibility of false positive results, especially outside of influenza season, perform confirmatory testing using RT-PCR or viral culture if immunofluorescence or rapid influenza diagnostic test results are positive.
- Viral culture should be performed if additional information on influenza viruses, such as influenza A virus subtype, antigenic characterization to compare with vaccine strains, or antiviral resistance data, are needed. Additionally, viral culture can be used to confirm results from rapid diagnostic testing (as mentioned above)
- Determining influenza virus type or subtype of influenza A virus can help inform antiviral therapy decisions.
- Test for other respiratory pathogens as well if it’s not influenza season.
- Once an outbreak has been identified, outbreak prevention and control measures should be implemented immediately.

Implement daily active surveillance for respiratory illness among ill residents, health care personnel and visitors to the facility.

- During an outbreak, once a single laboratory-confirmed case of influenza has been identified, it is likely there are other cases among exposed persons.
- Conduct daily active surveillance until at least 1 week after the last confirmed influenza case occurred.
- Test for influenza in the following:
  - Ill persons who are in the affected unit as well as previously unaffected units in the facility
  - Persons who develop acute respiratory illness symptoms more than 72 hours after beginning antiviral chemoprophylaxis
  - Note that elderly persons and other long-term care residents, including those who are medically fragile and those with neurological or neurocognitive conditions, may manifest atypical signs and symptoms with influenza virus infection, and may not have fever.
- Ensure that the laboratory performing the tests notifies the facility of tests results promptly.
Seasonal Influenza

- The local health and state health departments should be notified of every suspected or confirmed influenza outbreak in a long-term care facility, especially if a resident develops influenza while on or after receiving antiviral chemoprophylaxis.

Implement Standard and Droplet Precautions for all residents with suspected or confirmed influenza.

CDC’s guidance titled Prevention Strategies for Seasonal Influenza in Healthcare Settings contains details on the prevention strategies for all health care settings. Specific recommendations are highlighted below.

**Standard Precautions** are intended to be applied to the care of all patients in all health care settings, regardless of the suspected or confirmed presence of an infectious agent. Implementation of Standard Precautions constitutes the primary strategy for the prevention of healthcare-associated transmission of infectious agents among patients and health care personnel.

Examples of standard precautions include:

- Wearing gloves if hand contact with respiratory secretions or potentially contaminated surfaces is anticipated.
- Wearing a gown if soiling of clothes with a resident’s respiratory secretions is anticipated.
- Changing gloves and gowns after each resident encounter and performing hand hygiene.
- Performing hand hygiene before and after touching the resident, after touching the resident’s environment, or after touching the resident’s respiratory secretions, whether or not gloves are worn. Gloves do not replace the need for performing hand hygiene.

**Droplet Precautions** are intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions. Droplet Precautions should be implemented for residents with suspected or confirmed influenza for 7 days after illness onset or until 24 hours after the resolution of fever and respiratory symptoms, whichever is longer, while a resident is in a health care facility.

Examples of Droplet Precautions include:

- Placing ill residents in a private room. If a private room is not available, place (cohort) residents suspected of having influenza residents with one another;
- Wearing a facemask (e.g., surgical or procedure mask) upon entering the resident’s room. Remove the facemask when leaving the resident’s room and dispose of the facemask in a waste container.
- If resident movement or transport is necessary, have the resident wear a facemask (e.g., surgical or procedure mask), if possible.
- Communicate information about patients with suspected, probable, or confirmed influenza to appropriate personnel before transferring them to other departments.

These Precautions are part of the overall infection control strategy to protect against influenza in health care settings and should be used along with other infection control measures, such as isolation or cohorting of ill residents, screening employees and visitors for illness, furloughing ill health care personnel, and discouraging ill visitors from entering the facility.

In some cases, facilities may choose to apply Standard Precautions and Droplet Precautions for longer periods based on clinical judgment, such as in the case of young children or severely immunocompromised residents, who may shed influenza virus for longer periods of time.

Because residents with influenza may continue to shed influenza viruses while on antiviral treatment, infection control measures to reduce transmission, including following Standard and Droplet Precautions, should continue while the resident is taking antiviral therapy. This will also reduce transmission of viruses that may have become resistant to antiviral drugs during therapy.
Administer influenza antiviral treatment and chemoprophylaxis to residents and health care personnel according to current recommendations.

**All long-term care facility residents who have confirmed or suspected influenza should receive antiviral treatment immediately.**

Treatment should not wait for laboratory confirmation of influenza.

Antiviral treatment works best when started within the first 2 days of symptoms. However, these medications can still help when given after 48 hours to those that are very sick, such as those who are hospitalized, or those who have progressive illness.

Three influenza antiviral drugs approved by the U.S. Food and Drug Administration are recommended for use in the United States: oral oseltamivir (available as a generic version or under the trade name Tamiflu®), as a pill or suspension; zanamivir (trade name Relenza®), available as an inhaled powder using a disk inhaler device; and intravenous peramivir (trade name Rapivab®). It should be noted that some long-term care residents may have difficulty using the inhaler device for zanamivir.

Amantadine and rimantadine are **NOT** recommended for use because of high levels of antiviral resistance among circulating influenza A viruses.

The recommended dosing and duration of antiviral treatment is twice daily for 5 days. Longer treatment courses for patients who remain severely ill after 5 days of treatment can be considered. Dosage adjustment may be required for children and persons with certain underlying conditions.Clinicians should consult the manufacturers’ package insert for recommended drug dosing adjustments and contraindications.

Having preapproved orders from physicians or plans to obtain orders for antiviral medications on short notice can substantially expedite administration of antiviral medications.

For more information on the antiviral agents see Recommended Dosage and Duration of Treatment or Chemoprophylaxis for Influenza Antiviral Medications.

**All eligible residents in the entire long-term care facility (not just currently impacted wards) should receive antiviral chemoprophylaxis as soon as an influenza outbreak is determined.**

When at least 2 patients are ill within 72 hours of each other and at least one resident has laboratory-confirmed influenza, the facility should promptly initiate antiviral chemoprophylaxis to all non-ill residents, regardless of whether they received influenza vaccination during the previous fall. Priority should be given to residents living in the same unit or floor as an ill resident. However, since staff and residents may spread influenza to residents on other units, floors, or buildings of the same facility, all non-ill residents are recommended to receive antiviral chemoprophylaxis to control influenza outbreaks. Antiviral chemoprophylaxis is recommended for all non-ill residents, regardless of their influenza vaccination status, in long-term care facilities that are experiencing outbreaks.

Antiviral chemoprophylaxis is meant for patients and residents who are not exhibiting influenza-like illness but who may be exposed or who may have been exposed to an ill person with influenza, to prevent transmission.

Use of antiviral drugs for chemoprophylaxis of influenza is a key component of influenza outbreak control in institutions that house residents at higher risk of influenza complications. While highly effective, antiviral chemoprophylaxis is not 100% effective in preventing influenza illness.

CDC recommends antiviral chemoprophylaxis for a minimum of 2 weeks, and continuing for at least 7 days after the last known case was identified.

Persons whose need for chemoprophylaxis is attributed to potential exposure to a person with laboratory-confirmed 2009 H1N1, influenza A (H3N2), or influenza B should receive oseltamivir or zanamivir. Zanamivir should be used when persons require chemoprophylaxis as a result of exposure to influenza virus strains that are suspected of being oseltamivir-resistant.

(For more information see **Recommended Dosage and Duration of Treatment or Chemoprophylaxis for Influenza Antiviral Medications** or the **IDSA guidelines**.)
Antiviral chemoprophylaxis can be considered or offered to unvaccinated personnel who provide care to persons at high risk of complications.

While CDC recommends judicious use of antiviral medications for chemoprophylaxis to reduce the possibility of development and spread of antiviral resistant influenza viruses, chemoprophylaxis may be considered for all employees, regardless of their influenza vaccination status, if the outbreak is caused by a strain of influenza virus that is not well matched by the vaccine.

Antiviral chemoprophylaxis should also be considered in personnel for whom influenza vaccine is contraindicated.

An emphasis on early treatment is an alternative to chemoprophylaxis in managing certain persons who have had a suspected exposure to influenza virus. Health care personnel who have occupational exposures can be counseled about the early signs and symptoms of influenza and advised to contact their health-care provider immediately for evaluation and possible early treatment if clinical signs or symptoms develop.

For newly vaccinated staff, antiviral chemoprophylaxis can be administered up to 2 weeks following influenza vaccination with TIV. Persons receiving antiviral chemoprophylaxis should not receive live attenuated influenza virus vaccine (LAIV), and persons receiving LAIV should not receive antiviral treatment or chemoprophylaxis until 14 days after LAIV administration.

The latest CDC antiviral recommendations are available on [CDC’s influenza antiviral drugs page for health professionals](https://www.cdc.gov/flu/professionals/antivirals/index.htm).

Be Aware of the Possibility of a Drug-Resistant Virus

Residents receiving antiviral medications who do not respond to treatment or who become sick with influenza after starting chemoprophylaxis might have an infection with an antiviral-resistant influenza virus.

To limit the potential transmission of antiviral drug-resistant influenza virus, whether in chronic or acute-care settings or other closed settings, measures should be taken to reduce contact between ill persons taking antiviral drugs for treatment and other persons, including those receiving antiviral chemoprophylaxis.

Infection-control measures are especially important for patients who are immunocompromised to reduce the risk for transmission of oseltamivir-resistant viruses.

Notify the health department if a resident develops influenza while on or after receiving antiviral chemoprophylaxis.

Consider the following additional measures to reduce transmission among residents and health care personnel:

- Have symptomatic residents stay in their own rooms as much as possible, including restricting them from common activities, and have their meals served in their rooms when possible.
- Limit the number of large group activities in the facility and consider serving all meals in resident rooms if possible when the outbreak is widespread (involving multiple units of the facility).
- Avoid new admissions or transfers to wards with symptomatic residents.
- Limit visitation and exclude ill persons from visiting the facility via posted notices. Consider restricting visitation by children during community outbreaks of influenza.
- Monitor personnel absenteeism due to respiratory symptoms and exclude those with influenza-like symptoms from work until at least 24 hours after they no longer have a fever.
- Restrict personnel movement from areas of the facility having illness to areas not affected by the outbreak.
- Administer the current season’s influenza vaccine to unvaccinated residents and health care personnel as per current vaccination recommendations. For the latest information on influenza vaccination, see [CDC’s seasonal influenza vaccination resources for health professionals page](https://www.cdc.gov/flu/vaccines/prek-12/).  

*Patients with illness associated with influenza virus infection often have fever or feverishness with cough, chills, headache, myalgias, sore throat, or runny nose. Some patients, such as the elderly, children with neuromuscular disorders, and young infants, may have atypical clinical presentations.
Seasonal Influenza

Resources

**Vaccine**

Seasonal Influenza Vaccination Resources for Health Professionals (https://www.cdc.gov/flu/professionals/vaccination/index.htm)

Prevention and Control of Influenza with Vaccines. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010: Nursing Homes and Other Long-Term Care Facilities. MMWR 2010:59(RR08);1-62

CDC. Immunization of Health-Care Personnel. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011:60(RR07);1-45

**Antiviral Drugs**


Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America


Recommendations of the Advisory Committee on Immunization Practices (ACIP): Antiviral Drug Information for Health Care Professionals: Control of Influenza Outbreaks in Institutions. MMWR 2011:60(RR01);1-24

**Testing**


**Infection Control**

Prevention Strategies for Seasonal Influenza in Healthcare Settings (https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm)


**Reported Outbreaks in Long-Term Care Facilities**

CDC. Outbreaks of 2009 Pandemic Influenza A (H1N1) Among Long-Term Care Facility Residents --- Three States, 2009. MMWR 2010:59(03):74-77

**Additional References**


## CDC Influenza and Pneumonia Recommendations & Schedule - IMMUNOCOMPETENT* patients >65 years

The full CDC Adult Vaccination Schedule including recommendations for patients <65 years and for other vaccines, is available at [https://www.cdc.gov/vaccines/schedules/easy-to-read/adult.html](https://www.cdc.gov/vaccines/schedules/easy-to-read/adult.html)

<table>
<thead>
<tr>
<th>Influenza</th>
<th>Recommended every year as soon as it is available</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Admissions during late flu season (February and March) are still recommended</td>
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<tr>
<td></td>
<td>Admissions outside of the flu season may be administered at the facility’s discretion</td>
</tr>
</tbody>
</table>

### Pneumonia

Two bacterial pneumonia vaccinations are available. ACIP expects administration of both PCV12 and PPSV23 will provide optimal protection against pneumococcal infections. The recommendations for adults aged <65 years are different than for adults aged >65 years so they should be vaccinated based on the ACIP recommendations for their age group. If pneumonia administration is unknown or incomplete, PCV13 and PPSV23 should be administered.

<table>
<thead>
<tr>
<th>Pneumonia Vaccine</th>
<th>Patients who have already received Prevnar</th>
<th>Patients who have already received Pneumovax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naïve Patients AND Patients with Unknown Immunization History</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevnar (PCV13)</td>
<td>Administer as soon as possible (before Pneumovax)</td>
<td>Do not administer again</td>
</tr>
<tr>
<td>Pneumovax (PPSV23)</td>
<td>Administer at least 1 year after Prevnar</td>
<td>Administer at least 1 year after Prevnar</td>
</tr>
</tbody>
</table>

* Review the Special Populations section for pneumococcal vaccination in the CDC Adult Vaccination Schedule footnotes to determine if the patient qualifies as IMMUNOCOMPETENT
# Influenza Adult Immunization Guide | 2018-2019

**VAERS**

**Vaccine Adverse Event Reporting System**

**www.vaers.hhs.gov**

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**INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE**

1. **Patient name:** (first) (last)
2. **Date of birth:** (mm/dd/yyyy)
3. **Sex:** ☐ Male ☐ Female ☐ Unknown
4. **Date and time of vaccination:** (mm/dd/yyyy) ☐ AM ☐ PM
5. **Age at vaccination:** Years Months
6. **Date and time adverse event started:** (mm/dd/yyyy) ☐ AM ☐ PM
7. **Today’s date:** (mm/dd/yyyy)
8. **Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:**
9. **Allergies to medications, food, or other products:**
10. **Other illnesses at the time of vaccination and up to one month prior:**
11. **Chronic or long-standing health conditions:**
12. **Has the patient recovered from the adverse event(s)?:** ☐ Yes ☐ No ☐ Unknown
13. **Describe the adverse event(s), treatment, and outcome(s), if any:** (symptoms, signs, time course, etc.)
14. **Medical tests and laboratory results related to the adverse event(s):** (include dates)
15. **Result or outcome of adverse event(s):** (Check all that apply).
16. **Has the patient recovered from the adverse event(s)?:** ☐ Yes ☐ No ☐ Unknown
17. **Any other vaccines received within one month prior to the date listed in item 4:** (Route is HOW vaccine was given, Body site is WHERE vaccine was given).
18. **Describe the adverse event(s), treatment, and outcome(s), if any:** (symptoms, signs, time course, etc.)
19. **Medical tests and laboratory results related to the adverse event(s):** (include dates)
20. **Result or outcome of adverse event(s):** (Check all that apply).
21. **Has the patient recovered from the adverse event(s)?:** ☐ Yes ☐ No ☐ Unknown
22. **Any other vaccines received within one month prior to the date listed in item 4:** (Route is HOW vaccine was given, Body site is WHERE vaccine was given).
23. **Has the patient ever had an adverse event following any previous vaccine?:** (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name).
24. **Patient’s race:**
   - ☐ American Indian or Alaska Native
   - ☐ Asian
   - ☐ Black or African American
   - ☐ Native Hawaiian or Other Pacific Islander
25. **Patient’s ethnicity:**
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino
   - ☐ Unknown
26. **Immuniz. proj. report no.:** (Health Dept use only)
27. **Status at vaccination:**
   - ☐ Active duty
   - ☐ Reserve
   - ☐ National Guard
   - ☐ Beneficiary
   - ☐ Other
28. **Vaccinated at Military/DoD site:** ☐ Yes ☐ No

---

**INFORMATION ABOUT THE PERSON COMPLETING THIS FORM**

13. **Relation to patient:** ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other:
14. **Best doctor/healthcare professional to contact about the adverse event:** Name: Phone: ( ) Ext:
15. **Facility/clinic name:**
16. **Type of facility:** (Check one).
17. **Facility/clinic phone:** ( ) Ext:
18. **Facility/clinic fax:**
19. **Facility/clinic email:**
20. **Facility/clinic street address:**
21. **Facility/clinic city:**
22. **Facility/clinic state:**
23. **Facility/clinic ZIP code:**
24. **Facility/clinic type:**
   - ☐ Doctor’s office or hospital
   - ☐ Pharmacy or drug store
   - ☐ Worksite clinic
   - ☐ Public health clinic
   - ☐ Nursing home or senior living facility
   - ☐ School/student health clinic
   - ☐ Other:
   - ☐ Unknown

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**INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN**

16. **Type of facility:** (Check one).
17. **Doctor or other healthcare professional office/clinic visit**
18. **Emergency room or emergency department visit**
19. **Hospitalization:**
   - ☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
   - ☐ Life threatening illness (immediate risk of death from the event)
   - ☐ Disability or permanent damage
   - ☐ Congenital anomaly or birth defect
   - ☐ None of the above

---

**WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?**

17. **Enter all vaccines given on the date listed in item 4:** (Route is HOW vaccine was given, Body site is WHERE vaccine was given).
18. **Describe the adverse event(s), treatment, and outcome(s), if any:** (symptoms, signs, time course, etc.)
19. **Medical tests and laboratory results related to the adverse event(s):** (include dates)
20. **Result or outcome of adverse event(s):** (Check all that apply).
21. **Has the patient recovered from the adverse event(s)?:** ☐ Yes ☐ No ☐ Unknown
22. **Any other vaccines received within one month prior to the date listed in item 4:** (Route is HOW vaccine was given, Body site is WHERE vaccine was given).
23. **Has the patient ever had an adverse event following any previous vaccine?:** (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name).
24. **Patient’s race:**
   - ☐ American Indian or Alaska Native
   - ☐ Asian
   - ☐ Black or African American
   - ☐ Native Hawaiian or Other Pacific Islander
25. **Patient’s ethnicity:**
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino
   - ☐ Unknown
26. **Immuniz. proj. report no.:** (Health Dept use only)
27. **Status at vaccination:**
   - ☐ Active duty
   - ☐ Reserve
   - ☐ National Guard
   - ☐ Beneficiary
   - ☐ Other
28. **Vaccinated at Military/DoD site:** ☐ Yes ☐ No

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**ADDITIONAL INFORMATION**

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**COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS**

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**FORM FDA VAERS 2.0 (6/17)**
### VAERS

**CONTINUATION PAGE** (Use only if you need more space from the front page).

<table>
<thead>
<tr>
<th>Vaccine (type and brand name)</th>
<th>Manufacturer</th>
<th>Lot number</th>
<th>Route</th>
<th>Body site</th>
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<tbody>
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**Use the space below to provide any additional information (indicate Item number):**

---

**FORM FDA VAERS 2.0 (8/17)***
COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

• Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile.
• If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
• If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to info@vaers.org.
• Fill out the VAERS form as completely as possible and use the Continuation Page if needed. Use a separate VAERS form for each individual patient.
• If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
• You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
• Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
• Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
• Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed.

• Items 4 and 5: Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don’t know the day). If you do not know the exact time, but know it was in the morning (“AM”) or afternoon or evening (“PM”), please provide that information.
• Item 6: If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient’s date of birth (Item 2) and date and time of vaccination (Item 4).
• Item 8: If the report is about a vaccine given to a pregnant woman, select “Yes” and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select “No” or “Unknown.”
• Item 9: List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/alternative medicines being taken by the patient when the vaccine(s) was given.
• Item 10: List any allergies the patient has to medications, foods, or other products.
• Item 11: List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does NOT include the adverse event you are reporting.
• Item 12: List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
• Item 13: List the name of the person who is completing the form. Select the “Check if same as item 1” box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
• Item 14: List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
• Item 15: Select the “Check if same as item 13” box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
• Item 16: Select the option that best describes the type of facility where the vaccine(s) was given.
**Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:
- Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)
- By mouth/oral
- In nose/intranasal
- Other (specify)
- Unknown

For body site, the options include:
- Right arm
- Left arm
- Arm (side unknown)
- Right thigh
- Left thigh
- Thigh (side unknown)
- Nose
- Mouth
- Other (specify)
- Unknown

For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named “Dose no. in series.”

**Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).

**Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.

**Item 20:** Select “Yes” if the patient’s health is the same as it was prior to the vaccination or “No” if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select “Unknown” if the patient’s present condition is not known.

**Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select “None of the above.” Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.

**Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.

**Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.

**Item 24:** Check all races that apply.

**Item 25:** Check the single best answer for ethnicity.

**Item 26:** For health department use only.

**Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

**GENERAL INFORMATION**
- VAERS ([www.vaers.hhs.gov](http://www.vaers.hhs.gov)) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see [www.hrsa.gov/vaccinecompensation/index.html](http://www.hrsa.gov/vaccinecompensation/index.html)).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.