PharMerica®

Influenza Adult Immunization Guide | 2019-2020

General

Seasonal Influenza

Additional Info

Purpose of this Guide

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 Department of 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 and §483.80(d) Influenza and Pneumococcal Immunizations can be viewed at: State Operations Manual - Appendix PP. For influenza, residents must be offered the immunization between October 1 and March 31 on an annual basis unless the resident has already been immunized during that time frame or it is medically contraindicated. However, regulatory guidance from the CDC notes that influenza vaccine should be administered when it becomes available, rather than on a specific date.

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 healthcare professional trained to screen patients for contraindications to vaccination, administer vaccine, 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 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

	VACCINE PREVENTABLE DISEASE	PRODUCTS COVERED
PART B	Influenza	Quadrivalent, High-dose, Adjuvant
	Pneumococcal	Prevnar 13, Pneumovax 23
	Hepatitis B*	Energix-B, Recombivax HB
	** Patients at medium to high risk for infection as designated by Medicare*	
PART D	Hep A/Hep B	Twinrix
	Herpes Zoster	Zostavax, Shingrix
	HPV	Cervarix, Gardasil
	Tdap	Adacel, Boostrix
	Meningococcal	Menactra, Menveo, Menomune
	Others	All commercially available vaccines not covered by Part B; co-pays may apply
PART B WITH CLINICAL REVIEW	Rabies	Imovax, RabAvert
	Hep A	Havrix, VAQTA
	Tetanus Toxoid	Tetanus Toxoid
	Anthrax	BioThrax

2019-2020 Influenza Vaccinations

Summary of Influenza Vaccines
CDC recommends annual influenza vaccination for everyone six months and older with any licensed, age-appropriate flu vaccine, with no preference expressed for any one vaccine over another.1 The standard trivalent vaccine is no longer manufactured; however, quadrivalent, high-dose trivalent, and adjuvanted trivalent formulations are available.

Quadrivalent Vaccine
The quadrivalent flu vaccine targets four influenza strains—two *influenza A* viruses and two *influenza B* viruses — to provide broader coverage against an additional B strain than the previous standard trivalent flu vaccine. There are vaccines in this group that are FDA-approved for use in those as young as six months of age.

Flucelvax™ is a quadrivalent flu vaccine that uses mammalian cultured cells (Madin-Darby Canine Kidney cells) instead of the traditional egg-based approach to grow the vaccine virus. The original vaccine virus is initially grown in egg cells so this product is not considered egg-free.2

Flublock™ is a quadrivalent flu vaccine that is the only egg-free vaccine on the U.S. market. Its production involves the use of genetic material from the recommended influenza viruses and insect cells to grow the vaccine virus.[3]

Trivalent Vaccine (Adjuvanted)
FLUAD™ is a non-high-dose trivalent inactivated flu vaccine for adults 65 years of age and older that contains an adjuvant designed to elicit a greater immune response to vaccination. Past studies that tested FLUAD's™ ability to generate a greater immune response against an influenza virus saw comparable antibody levels to the unadjuvanted trivalent seasonal flu vaccines (e.g., Agriflu).6

Trivalent Vaccine (High-Dose)
FLUZONE HD™ is a high-dose trivalent vaccine that contains four times the amount of antigen, indicated for persons 65 years of age and older due to their weakened immune systems.4

When compared to the standard-dose trivalent influenza vaccine, studies have associated high-dose (HD) trivalent influenza vaccines with a 24.2% increase in protection against influenza illness, significantly higher (1.8:1) mean HAI antibody titers, and 4.8% higher seroprotection in adults 65 years of age and older. [5]

As of the 2019-2020 influenza season, standard trivalent vaccines are no longer available from any manufacturer.

Storage & Handling

Influenza vaccines should be protected from light and stored at temperatures that are recommended on the package insert. These recommended storage temperatures are generally 2°C to 8°C (36°F to 46°F), and should be maintained at all times with adequate refrigeration and temperature monitoring. Vaccine that has frozen should be discarded. Additionally, vaccines should not be used beyond the expiration date on the label.

Some vaccines are available in multi-dose vials. These multi-dose vials also might have a beyond use date, which specifies the number of days the vaccine can be kept once the vial stopper is first accessed. Once accessed for the first dose, multi-dose vials should not be used after the beyond use date.

References

1. Centers for Disease Control and Prevention. Influenza (Flu). 23 Aug 2018. Web. 25 Feb 2019. https://www.cdc.gov/flu/protect/keyfacts.htm
2. Centers for Disease Control and Prevention. Cell-Based Flu Vaccines. 4 Oct 2018. Web. 25 Feb 2019. https://www.cdc.gov/flu/protect/vaccine/cell-based.htm
3. Centers for Disease Control and Prevention. Recombinant Flu Vaccine. 4 Oct 2018. Web. 25 Feb 2019. https://www.cdc.gov/flu/protect/vaccine/qa_flublok-vaccine.htm
4. U.S. Food & Drug Administration. Vaccines, Blood & Biologics. 10 Mar 2017. Web. 11 May 2017. https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm112854.htm
5. DiazGranados, C., et al. Efficacy of High-Dose versus Standard-Dose Influenza Vaccine in Older Adults. New England Journal of Medicine. 14 Aug 2014. Web. 10 May 2017. http://www.nejm.org/doi/full/10.1056/NEJMoa1315727?query=featured_home#t=article
6. FLUAD [package insert]. Seqirus USA. Aug 2017. Web. 25 Feb 2019. http://labeling.seqirus.com/PI/US/FLUAD/EN/FLUAD-Prescribing-Information.pdf

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 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 women, 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.

Each 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 Influenza vaccine

CDC recommends everyone 6 months of age 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.

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

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. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3 Talk with your healthcare provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**.
- Has ever had **Guillain-Barré Syndrome** (also called GBS).

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

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 healthcare provider can give you more information.

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

4 Risks of a vaccine reaction

- Soreness, redness, and swelling where shot is given, fever, muscle aches, and headache can happen after influenza vaccine.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

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. Tell your healthcare provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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 healthcare provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your healthcare 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 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. 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. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider.
- 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 **www.cdc.gov/flu**

Vaccine Information Statement (Interim)

Inactivated Influenza Vaccine

Office use only

8/15/2019 | 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 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 (e.g. MMR, Rotarix, Zostavax)? ❑ *YES ❑ NO

*If YES, recommend 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(s) 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(s) 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:_____

PharMerica®

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.

PharMerica®

Interim Guidance for Influenza Outbreak Management in Long-term Care and Post-acute Care Facilities

The following guidance is from the 2018-2019 influenza season. Please see Recommendations of the Advisory Committee on Immunization Practices – United States, 2018-2019 Season for the latest information regarding recommended influenza vaccines. Please see Antiviral Drugs: Information for Healthcare Professionals for the current summary of recommendations for clinical practice regarding the use of influenza antiviral medications. Please also refer to the Infectious Diseases Society of America (IDSA) 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza.

Long-term care facilities may be defined as institutions, such as nursing homes and skilled nursing facilities, that provide healthcare 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, healthcare workers and visitors. Spread of influenza can occur between and among residents, healthcare 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 healthcare settings, including in long-term care facilities, requires a multi-faceted approach that includes the following:

- Influenza Vaccination
- Influenza Testing
- Infection Prevention and Control Measures
- Antiviral Treatment
- Antiviral Chemoprophylaxis

Before an Outbreak Occurs

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

Residents

If possible, all residents should receive inactivated influenza vaccine (IIV) annually before influenza season. For persons aged ≥65 years, any age-appropriate IIV formulation (standard-dose or high-dose, trivalent or quadrivalent, unadjuvanted or adjuvanted) or quadrivalent recombinant influenza vaccine are acceptable options. In the majority of seasons, influenza vaccines will become available to long-term care facilities beginning in September, and influenza vaccination should be offered by the end of October. Informed consent is required to implement a standing order for vaccination, but this does not necessarily mean a signed consent must be present. Although vaccination by the end of October is recommended, influenza vaccine administered in December or later, even if influenza activity has already begun, is likely to be beneficial in the majority of influenza seasons because the duration of the season is variable, and influenza activity might not occur in certain communities until February or March.

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 the 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 shortage. This information is to be reported as part of the CMS Minimum Data Set, which tracks nursing home health parameters.

Healthcare Personnel

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

- Healthcare personnel who get vaccinated may 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 complications

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. 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 of influenza virus infection (e.g. behavior change), and may not have a fever.

Influenza Testing

Even if it's not influenza season, influenza testing should occur when any resident has signs and symptoms of acute respiratory illness or influenza-like illness. Information about influenza testing is available at: https://www.cdc.gov/flu/professionals/diagnosis/index.htm. More information about testing is included below.

When There Is a Confirmed or Suspected Influenza Outbreak (Two or More Ill Residents)

If one laboratory-confirmed influenza positive case is identified along with other cases of acute respiratory illness in a unit of a long-term care facility, an influenza outbreak might be occurring. Active surveillance for additional cases should be implemented as soon as possible once one case of laboratory-confirmed influenza is identified in a facility. When two cases of laboratory-confirmed influenza are identified within 72 hours of each other in residents on the same unit, outbreak control measures should be implemented as soon as possible.

Implementation of outbreak control measures can also be considered as soon as possible when one or more residents have acute respiratory illness with suspected influenza and the results of influenza molecular tests are not available the same day of specimen collection. While unusual, an influenza outbreak can occur outside of the normal influenza season; therefore, testing for influenza viruses and other respiratory pathogens should also be performed 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.

*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 of influenza virus infection (e.g. behavior change), and may not have a fever (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

- Determine if influenza virus is the causative agent by performing influenza testing on upper respiratory tract specimens (i.e. nasopharyngeal swabs, nasal swabs, nasopharyngeal or nasal aspirates, or combined nasal and throat swabs) of ill residents with recent onset of signs and symptoms suggestive of influenza or acute respiratory illness.
- The following influenza tests are recommended: molecular assays, including rapid molecular assays, other molecular tests, or reverse transcription polymerase chain reaction (RT-PCR).
- If influenza molecular assays are not available and antigen detection tests are used such as rapid influenza diagnostic tests (RIDTs) or immunofluorescence assays, false negative results can occur because RIDTs and immunofluorescence assays have lower sensitivity than molecular assays for detection of influenza viruses. If influenza is suspected and RIDTs or immunofluorescence results are negative, perform confirmatory testing using molecular influenza assays. Information on influenza diagnostic testing is available online or by contacting your state public health laboratory.
- Influenza testing with molecular assays such as RT-PCR may be available at a local or state public health laboratory.
- Viral culture should be performed at a public health laboratory if additional information on influenza viruses, such as influenza A virus subtype, antigenic characterization to compare with influenza vaccine strains, or antiviral resistance data, are needed.
- Determining influenza virus type or subtype of influenza A virus can help inform antiviral therapy decisions.

Implement Daily Active Surveillance for Acute Respiratory Illness Among All Residents, Healthcare Personnel and Visitors to the Facility.

- During an outbreak, once a single laboratory-confirmed case of influenza has been identified in a resident, it is likely there are other cases among exposed persons.
- Conduct daily active surveillance until at least one week after the last laboratory-confirmed influenza case was identified.
- Test for influenza with a molecular assay in the following:
  - Ill persons who are in the affected unit(s) as well as previously unaffected units in the facility
  - Persons who develop acute respiratory illness symptoms 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 of influenza virus infection (e.g. behavior change), and may not have a fever.

- Ensure that the laboratory performing influenza testing notifies the facility of test results promptly.
- The local public 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 healthcare settings. Specific recommendations are highlighted below.

Standard Precautions are intended to be applied to the care of all patients in all healthcare 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 healthcare 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 seven 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 healthcare facility.

Examples of Droplet Precautions include:

- Place ill residents in a private room. If a private room is not available, place (cohort) residents suspected of having influenza residents with one another.
- Wear 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.
- f 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 healthcare 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 healthcare 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 Healthcare Personnel According to Current Recommendations.

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

Initiation of antiviral treatment should not wait for laboratory confirmation of influenza.

Antiviral treatment works best when started within the first two 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, those who have progressive illness, or those who are at high risk for complications of influenza. (https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm)

Four influenza antiviral drugs approved by the U.S. Food and Drug Administration are recommended for treatment of uncomplicated influenza in the United States: neuraminidase inhibitors: 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®); and a cap-dependent endonuclease inhibitor: baloxavir marboxil (trade name Xofluza®). 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 to these drugs among circulating influenza A viruses.

The recommended dosing and duration of antiviral treatment is twice daily for five days for neuraminidase inhibitors (oseltamivir and zanamivir), and one dose for intravenous peramivir. A single oral dose of baloxavir is equivalent to five days of twice-daily oral oseltamivir. Longer antiviral treatment courses for hospitalized patients who remain severely ill after five 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 inserts for approved ages, recommended drug dosing adjustments and contraindications.

In the setting of an influenza outbreak, empiric antiviral treatment should be given as soon as possible without waiting for influenza testing results, especially if results will not be available on the day of specimen collection.

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 CDC's influenza antiviral medication page for health professionals.

All exposed residents on units or wards with influenza cases in the long-term care facility (currently impacted wards) should receive antiviral chemoprophylaxis as soon as an influenza outbreak is determined (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

When at least two 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 with oral oseltamivir to all non-ill residents living on the same unit as the resident with laboratory-confirmed influenza (outbreak affected units), regardless of whether they received influenza vaccination during the current season. Consideration may be given for extending antiviral chemoprophylaxis to residents on other unaffected units or wards in the long-term care facility based upon other factors (e.g. unavoidable mixing of residents or staff from affected units and unaffected units).

Antiviral chemoprophylaxis is meant for 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 two weeks and continuing for at least seven days after the last known laboratory-confirmed influenza case was identified on affected units.

Persons whose need for chemoprophylaxis is attributed to potential exposure to a person with laboratory-confirmed influenza should receive oral oseltamivir or inhaled zanamivir. Zanamivir should be used when persons require chemoprophylaxis as a result of exposure to influenza virus strains that are suspected or known to be oseltamivir-resistant.

(For more information, see Recommended Dosage and Duration of Treatment or Chemoprophylaxis for Influenza Antiviral Medications and (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935.)

Antiviral chemoprophylaxis can be considered or offered to unvaccinated personnel who provide care to persons at high risk of influenza 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 staff, 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, or based upon other factors (e.g. to reduce the risk of short staffing in facilities and units where clinical staff are limited and to reduce staff reluctance to provide care to residents with suspected or laboratory-confirmed influenza).

Antiviral Chemoprophylaxis Should Also Be Considered in Personnel for Whom Influenza Vaccine is Contraindicated.

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

For newly vaccinated staff, antiviral chemoprophylaxis can be considered for up to two weeks following inactivated influenza vaccination until vaccine-induced immunity is acquired. 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.

Be Aware of the Possibility of an Antiviral 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 an 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 prevention and 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 Healthcare 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 healthcare personnel as per current vaccination recommendations. For the latest information on influenza vaccination, see CDC's seasonal influenza vaccination resources for health professionals page.

*Patients with illness associated with influenza virus infection often have a 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. 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 of influenza virus infection (e.g. behavior change), and may not have a fever (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

CDC Influenza and Pneumococcal Recommendations & Schedule - Patients > 65 years

The full CDC Adult Vaccination Schedule, including recommendations for patients <65 years and for other vaccines, is available on the CDC website.

Influenza	Recommended every year as soon as it is available Admissions during late flu season (February & March) are still recommended Admissions outside of the flu season may be administered at the facility's discretion			
Pneumonia	Two types of vaccinations against bacterial pneumonia are available. ACIP expects administration of both PCV13 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 pneumococcal administration is unknown or incomplete, PCV13 and PPSV23 should be administered according to the below schedule.			
		Pneumonia Vaccine Naïve Patients AND Patients with Unknown Immunization History	**Patients Who Have Already Received Prevnar**	**Patients Who Have Already Received Pneumovax**
	Prevnar (PCV13)	Administer as soon as possible (before Pneumovax)	Do not administer again	Administer at least 1 year after Pneumovax
	Pneumovax (PPSV23)	Administer at least 1 year after Prevnar	Administer at least 1 year after Prevnar	Do not administer more than 1 dose to IMMUNOCOMPETENT patients > 65 years

** Review the Special Populations section under Pneumococcal vaccination of the CDC Adult Vaccination Schedule Footnotes to determine if the patient qualifies as IMMUNOCOMPETENT*

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items **2, 3, 4, 5, 6, 17, 18** and **21** are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use **Continuation Page** if needed).

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Phone: ( ) _____ Email: _____

2. Date of birth: (mm/dd/yyyy) _____ **3.** Sex: ☐ Male ☐ Female ☐ Unknown

4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM

5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM

6. Age at vaccination: ____Years ____Months **7.** Today's date: (mm/dd/yyyy) _____

8. Is the report about vaccine(s) given to a pregnant woman?: ☐ No ☐ Unknown ☐ Yes
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18).

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) _____

Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other: _____

Street address: _____ ☐ Check if same as item 1.
City: _____ State: _____ ZIP code: _____
Phone: ( ) _____ Email: _____

14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: ( ) _____ Ext: _____

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: _____
Fax: ( ) _____
Street address: ☐ Check if same as item 13. _____
City: _____
State: _____ ZIP code: _____
Phone: ( ) _____

16. Type of facility: (Check one).
☐ Doctor's office or hospital
☐ Pharmacy or drug store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School/student health clinic
☐ Other: _____
☐ Unknown

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). Use **Continuation Page** if needed.

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use **Continuation Page** if needed.

19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use **Continuation Page** if needed.

20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of adverse event(s): (Check all that apply).
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization: Number of days (if known) _____
Hospital name: _____
City: _____ State: _____
☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
☐ Life threatening illness (immediate risk of death from the event)
☐ Disability or permanent damage
☐ Patient died: Date of death _____ (mm/dd/yyyy)
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION (Use **Continuation Page** if needed).

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
select			select	select	select
select			select	select	select

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).
☐ No ☐ Unknown ☐ Yes _____

24. Patient's race: (Check all that apply). ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown ☐ Other: _____

25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

26. Immuniz. proj. report no.: (Health Dept use only). _____

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

27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other: _____

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS-2.0 (6/17)

SAVE

VAERS

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

17. Enter all vaccines given on the date listed in item 4 (continued):					Dose no. in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):					Dose no. in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

Use the space below to provide any additional information (indicate Item number): RETURN TO PAGE 1

FORM FDA VAERS-2.0 (6/17)

SAVE

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) 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).
- 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.