



Pneumococcal Vaccination

Pneumococcal Disease

Pneumococcal disease is caused by the bacterium *Streptococcus pneumoniae* (*S. pneumoniae*). *S. pneumoniae* can cause infections such as otitis media and sinusitis, as well as more invasive disease such as osteomyelitis or meningitis. In adults, pneumococcal disease most often presents as pneumonia, and pneumococcal pneumonia is the most common type of bacterial pneumonia in people living in nursing facilities (NFs).^{1,2}

Pneumococcal pneumonia is a major cause of illness, hospitalization, and death among adults. According to the Centers for Disease Control and Prevention (CDC), pneumococcal pneumonia leads to approximately 150,000 hospitalizations per year in the United States (US). Bacteremia (bacteria in the bloodstream) occurs in up to 25–30 percent of patients with pneumococcal pneumonia. There is a five to seven percent case-fatality rate, and this rate may be considerably higher in older adults.³

People aged 65 and older are at higher risk for pneumococcal pneumonia, as well as those under the age of 65 with certain conditions, including:⁴

- Chronic medical disorders, such as diabetes, heart disease, lung disease, liver disease or renal disease
- Cigarette smoking, alcoholism

Pneumococcal pneumonia is primarily spread by droplets from sneezing, coughing or other close contact. The incubation period is usually between one to three days and people may remain infectious as long as the bacteria is present in the respiratory secretions.^{1,5}

While vaccination cannot prevent every case of pneumococcal disease, research has shown pneumococcal vaccination can provide significant protection against pneumococcal pneumonia and invasive pneumococcal disease. Data on the effectiveness of newer pneumococcal vaccines (PCV15 and PCV20) are limited and mainly from clinical trials; however, real-world data are available demonstrating the effectiveness of the PCV13 and PPSV23.⁹

Regulatory Requirements

Federal

Federal regulations regarding pneumococcal vaccines can be found in [Appendix PP of the State Operations Manual \(SOM\)](#) at F883. These regulations require NF providers to develop policies and procedures that ensure each person or their representative:

- Has received education about the benefits and potential side effects of the pneumococcal vaccines
- Is offered the pneumococcal vaccine unless the person has already received the vaccine or has a medical contraindication
- Has an opportunity to refuse the vaccinations

Each person's medical record must include documentation that education was provided, including benefits and potential side effects. The facility must also document in the clinical record the vaccinations administered. If the pneumococcal vaccine was not given, the facility must document the refusal or the medical contraindication that prevented vaccination.

For more information, see the CMS Compliance Group, Inc. blog links below.^a

- [Ftag of the Week – F883 Influenza and Pneumococcal Vaccinations](#)

Note: Additional information on how surveyors review vaccinations is available in the *Infection Prevention, Control & Immunization Critical Element Pathway* found in the *Surveyor Resources* folder on the Centers for Medicare and Medicaid Services [\(CMS\) Nursing Homes page](#).

In addition, the National Vaccine Childhood Injury Act requires anyone administering a vaccination to provide the person receiving the vaccine (or their representative), regardless of their age, with a copy of the current Vaccine Information Statement (VIS) **prior** to giving the vaccine. The VIS is developed by the Centers for Disease Control and Prevention (CDC) and includes information about the risks and benefits of the vaccine, as well as steps that should be taken if an adverse reaction occurs.

- VIS – [Pneumococcal Conjugate Vaccine \(Interim\)](#): Issued 05/12/2023
- VIS – [Pneumococcal Polysaccharide Vaccine](#): Issued 10/30/2019

More information about the NVCIA and the requirements for using a VIS are available from [Immunize.org](#).

^a Any links, information, or advertisements provided by private entities throughout this resource do not infer endorsement or recommendation by Texas HHSC of any products or services.

- [You Must Provide Patients with Vaccine Information Statements \(VISs\) – It’s Federal Law!](#)

State

The Texas Administrative Code (TAC) also includes requirements for pneumococcal vaccinations of people living in a NF. [TAC Title 26, Part 1, Chapter 554, Subchapter Q, §554.1601 Infection Control](#) requires NF Providers to develop policies and procedures that include:

- Offering pneumococcal vaccination to those aged 65 or older if they have not previously been vaccinated
- Offering pneumococcal vaccination to people under the age of 65 who have not received a pneumococcal vaccination, but are candidates for vaccination due to a chronic medical condition
- Offering a second vaccination if recommended by a practitioner after assessment, if it has been over five years since the first vaccination was received
- Providing each person and/or their representative an opportunity to refuse vaccination
- Documentation of vaccinations in the clinical records
 - The person/representative received education about the risks (potential side effects) and benefits of vaccination
 - That the person received the vaccination or did not receive it due to a medical contraindication or refusal
 - Date the vaccination was received or date of refusal

QM NO20.02 Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine

Quality Measure (QM) NO20.02 reports the percentage of people who are up to date with their pneumococcal vaccine. This includes people who:

- Are up to date with their pneumococcal vaccine
- Have been offered the vaccine but declined
- Did not receive the vaccine due to a medical contraindication

The [Quality Measure Tip Sheet: Pneumonia Vaccine - Long & Short Stay](#) from TMF provides additional guidance in this measure.

CDC Guidelines – Pneumococcal Vaccines

[Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices – United States, 2022](#) outlines the detailed recommendations of the CDC’s Advisory Committee on Immunization Practices. Below is a summary of the recommendations relevant to NFs.

Currently, two types of pneumococcal vaccines are approved in the US for vaccinating adults:⁶

- Pneumococcal Conjugate Vaccines (PCV13, PCV15, PCV20)
- Pneumococcal Polysaccharide Vaccine (PPSV23)

People aged 65 and older, or those 19-64 with certain medical conditions who have not received a pneumococcal conjugate vaccine or have an unknown history should:^{7,9}

- Receive a dose of PCV20 or PCV15
- If PCV15 is given, a dose of PPSV 23 should follow
 - With at least one year between doses

More information about the timing of doses can be found on the [CDC website](#).

Older adults who received a PCV13 at any age **and** a dose of PPSV23 at age 65 or older, are eligible to receive the PCV20 as well. This option should be discussed with their physician to determine whether it should be given.^{7,8}

[Shared Clinical Decision-Making PCV20 Vaccination for Adults 65 Years or Older](#) provides additional details that can help guide the discussion between the person and his/her physician.

These recommendations are a recent change but are expected to provide better coverage than just the PPSV23 and PCV13 previously used in these populations.

Contraindications to immunization:⁹

- Severe, allergic reaction to a previous dose of a pneumococcal vaccine (such as an anaphylactic reaction)
- Severe allergic reaction to a vaccine containing diphtheria toxoid (PCV only)
- Allergy to any component of the vaccine

A person with a mild acute illness can receive the vaccine; however, if the illness is more severe, he/she and their physician should consider whether the benefits of receiving the vaccine while ill outweigh the risks.

Facility Immunization Systems

Documenting and Maintaining Records of Vaccination

Federal law requires documentation of vaccination in a person's clinical record, including:¹⁰

- Date of vaccination
- Name of the vaccine manufacturer and lot number
- Name, and title of the person administering the vaccine
- Address of the facility where the clinical record is kept
- Edition date of the VIS
- Date the VIS was provided to the person or his/her representative

The VIS may be provided in laminated, paper, or electronic/digital format, but must be given prior to administering the vaccine. The NF must offer a copy to the person receiving the vaccine to keep after receiving the vaccine, but he/she can decline to take it.¹¹

Best practices for documentation include the following (in addition to the federally required information). These are required by licensing rules and important for adverse event reporting.

- Vaccine type/name
- Route of administration (e.g., subcutaneous or intramuscular)
- Injection site (i.e., left deltoid muscle)
- Dosage given (volume, i.e., mL)

The facility should maintain personalized vaccination records for everyone living in the NF that include all of the above information. Vaccination records should be kept up to date, readily available and should not be thinned from the chart. Accurate and complete documentation will help facilities avoid vaccination errors and accidental re-vaccination.¹²

If the vaccine is administered outside of the NF, facility staff should attempt to obtain documentation from that provider. Immunize.org has developed a handout [*Tips for Locating Old Immunization Records*](#) that can help guide the search for documentation of prior vaccination. Self-reported doses of pneumococcal vaccine are acceptable; however, positive evidence of other vaccines is needed.¹³ A copy of the person's individual vaccination record should be sent with him/her at the time of discharge or when transferring to another facility.

If the person declines vaccination, the facility should document the education provided regarding the risks and benefits of vaccination.¹⁴ Documentation should

include evidence that the VIS/fact sheet was provided to them. This information can help the NF track the reasons for refusal and work to address related barriers.¹⁴ NFs may wish to implement a written declination form; [Refusal to Consent to Adult Vaccination: 19 Years and Older](#) is just one example of a declination form, developed by the Alliance for Immunization in Michigan.

Centralized immunization systems or logs provide an efficient way for NF to track vaccinations of people living in the facility. They can identify those who remain unvaccinated at any given time and can assist the NF in quickly determining which people need prophylaxis during an outbreak. In addition, a centralized system will allow staff to readily identify the vaccine serum lot numbers in the event of a vaccine recall.¹²

[ImmTrac2 Texas Immunization Registry](#) also covers adults. People who provide written consent can have their vaccine information stored electronically in a secure, confidential registry. Consent can be withdrawn at any time. ImmTrac2 also allows people to request a copy of their record at any time.

Managing Medical Emergencies Related to Vaccination

Adverse reactions to vaccines can vary from minor localized reactions (such as pain, redness, swelling, or itching at the injection site) to severe reactions involving anaphylaxis. Localized reactions can often be managed with interventions such as an over-the-counter analgesic for pain and a cool compress to the injection site to reduce redness and swelling.

Anaphylaxis can involve a range of symptoms and requires urgent treatment. Symptoms include:

- Hives, flushed skin
- Swelling of the lips, tongue or eyes
- Respiratory distress such as stridor, wheezing, shortness of breath
- Nausea, vomiting, diarrhea, abdominal pain
- Tachycardia, hypotension, dizziness or feeling lightheaded

NF staff must be prepared to manage medical emergencies related to administration of vaccines. The NF needs to have written protocols in place (such as policies and procedures or standing orders) and ensure staff have received training on those protocols.

The NF must have the medications and equipment available to respond to vaccine-related adverse reactions.¹⁵

- Epinephrine is the first line treatment for anaphylaxis, either through an autoinjector (e.g., an EpiPen® or generic equivalent) or another intramuscular formulation. After the initial injections, two additional doses of epinephrine may be given, with five to 15 minutes between doses.
- Necessary emergency equipment for performing CPR and maintaining a person’s airway must be available.

Immunize.org has published [Medical Management of Vaccine Reactions in Adults in a Community Setting](#). This resource can help the NF and its medical director develop facility-specific protocols for managing adverse reactions to vaccination.

Any adverse reactions and the treatment provided must be documented in the person’s clinical record.¹² Staff must also report certain adverse vaccine reactions to the federal [Vaccine Adverse Event Reporting System \(VAERS\)](#) regardless of the age of the person who received the vaccine.¹⁰ The [Table of Reportable Events Following Vaccination](#) provides more detail about reportable adverse reactions.

Additional Best Practices for Immunization Programs

The facility should designate a specific person/position to be responsible for coordinating all immunization activities in the NF.¹⁶ Responsibilities and tasks include:

- Providing input on the facility’s policies, procedures, and protocols related vaccination
- Logistics, including ordering vaccines and ensuring they are stored and handled correctly (according to manufacturer’s recommendations)
- Providing training for and [evaluating the competency](#) of staff who administer vaccines
- Coordinating the “messaging” about the facility’s immunization program to staff, physicians, people living in the NF/responsible parties
- Monitoring the effectiveness of the immunization program and identifying opportunities for improvement

In addition, the NF should have processes in place to ensure:

- Each person’s vaccination status is identified at the time of admission and offer any appropriate vaccine¹³
 - Includes locating documentation of vaccinations received outside of the NF (previous healthcare providers, community-based vaccination clinics, etc.)
- Facility-specific policies and procedures are implemented consistently
 - Use of standing orders or protocols for immunizations
 - Documentation of vaccination or declinations

- Educational resources for people receiving a vaccine or those who decline vaccination regarding the associated benefits and risk (for example, the current VIS)
- Re-approaching those who have previously declined, providing education on the benefits of vaccination and the risks associated with vaccine-preventable diseases

[Immunize.org](https://www.immunize.org) has resources available to help providers develop standing orders or protocols for their facility.

- [Ten Steps to Implementing Standing Orders for Immunization in Your Practice Setting](#)
- [Using Standing Orders for Administering Vaccines: What You Should Know](#)
- [Standing Orders for Administering Pneumococcal Vaccines \(PCV15, PCV20, and PPSV23\) to Adults](#)

The NF should establish goals and related metrics to ensure the program is effective and monitor the program processes and outcomes. Use the results to guide improvement efforts. For example:

- Percentage of people living in the facility who have received recommended pneumococcal vaccines
- Percentage of people living in the facility who did not receive a vaccination due to a medical contraindication
- Reasons given (other than a medical contraindication) for declining vaccination

Additional resources are available on the [Quality Monitoring Program Immunizations web page](#).

References

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