

## **Appendix P**

### **Task 2 - Entrance Conference**

4. For any survey conducted outside of the influenza season (October 1-March 31), obtain the name of the staff person who is responsible for coordinating and implementing the facility's immunization program to request a list of current residents who were in the facility during the previous influenza season, October 1 to March 31.

### **Sub-Task 5C – Resident Review**

#### **M. Review of Influenza and Pneumococcal Immunizations**

Use the Investigative Protocol contained at Tag F334 to complete a review of the implementation of the facility's immunization policies and procedures.

**F334**

**483.25(n) Influenza and pneumococcal immunizations**

**(1) Influenza. The facility must develop policies and procedures that ensure that --**

**(i) Before offering the influenza immunization, each resident, or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;**

**(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;**

**(iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and**

**(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:**

**(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and**

**(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.**

**(2) Pneumococcal disease. The facility must develop policies and procedures that ensure that --**

**(i) Before offering the pneumococcal immunization, each resident, or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;**

**(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;**

**(iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and**

**(iv) The resident's medical record includes documentation that indicated, at a minimum, the following:**

**(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and**

**(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.**

**(v) Exception As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident’s legal representative refuses the second immunization.**

**Intent:**

The intent of this requirement is to:

- Minimize the risk of residents acquiring, transmitting, or experiencing complications from influenza and pneumococcal pneumonia by assuring that each resident:
  - Is informed about the benefits and risks of immunizations; and
  - Has the opportunity to receive, unless medically contraindicated or refused or already immunized, the influenza and pneumococcal vaccine; and
- Assure documentation in the resident’s medical record of the information/education provided regarding the benefits and risks of immunization and the administration or the refusal of or medical contraindications to the vaccine(s).

**Definitions**

Medical contraindication – a condition or risk that precludes the administration of a treatment or intervention because of the substantial probability that harm to the individual may occur.

Precaution - a condition in a potential recipient that might increase the risk for a serious adverse reaction or that might compromise the vaccine’s induction of immunity. However, the risk for this happening is less than expected with a contraindication. For example, as a result of the resident’s condition, complications could result, or a person might experience a more severe reaction to the vaccine than would have otherwise been expected; however, the risk for this happening is less than expected with a medical contraindications.

**Overview**

Receipt of vaccinations is essential to the health and well-being of long term care residents. Establishing an immunization program facilitates achievement of this objective. Flu outbreaks place both the residents and the nursing facility staff at risk of infection. Pneumococcal pneumonia, a type of bacterial pneumonia, is a common cause of hospitalization and death in older people. People 65 years or older, are two to three times more likely than the younger population to get pneumococcal infections.

According to the Centers for Disease Control and Prevention (CDC), (see <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm>) “the primary option for

reducing the effect of influenza is immuno-prophylaxis with vaccine. Inactivated (i.e., killed virus) influenza vaccine and live, attenuated influenza vaccine are available for use in the United States .... Vaccinating persons at high risk for complications and their contacts each year before seasonal increases in influenza virus circulation is the most effective means of reducing the effect of influenza... When vaccine and epidemic strains are well-matched, achieving increased vaccination rates among persons living in closed settings (e.g., nursing homes and other chronic-care facilities) and among staff can reduce the risk for outbreaks by inducing herd immunity. Vaccination of health-care workers and other persons in close contact with persons at increased risk for severe influenza illness can also reduce transmission of influenza and subsequent influenza-related complications. Antiviral drugs used for chemoprophylaxis or treatment of influenza are a key adjunct to vaccine ... However, antiviral medications are not a substitute for vaccination.”

Because of the clinically complex conditions of most nursing home residents, it is especially important for the facility to have a program in place for the prevention of disease. The Long Term Care regulations at 42 CFR 483.65 (F441) Infection Control, requires that each “facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection. The regulation for immunization complements this existing infection control regulation in the areas of prevention of the development and transmission of disease. (For more information on immunizations programs, see <http://www.cdc.gov/nip/publications/long-term-care.pdf>.)

An effective immunization program involves collaborating with the medical director to develop resident care policies for immunization(s) that reflect current standards of practice and that include:

- Physician approved policies for orders for influenza and pneumococcal polysaccharide vaccines (administration must be based on an assessment of each resident for possible medical contraindications - See F386 for physician orders for vaccinations);
- Identification, of each resident’s immunization status, including assessment for potential medical contraindications and record of vaccination;
- The vaccination schedule including mechanisms for recording and monitoring for administration of both influenza and pneumococcal pneumonia vaccines; and
- How pertinent information will be provided to residents. The facility may wish to use educational resources such as those provided by the U. S. Centers for Disease Control:
  - For trivalent inactivated vaccine (TIV):  
<http://www.cdc.gov/nip/publications/VIS/vis-flu.pdf>,

- For live attenuated vaccine (LAIV)LAIV:  
<http://www.cdc.gov/nip/publications/VIS/vis-flulive.pdf> ; and
- For pneumococcal polysaccharide vaccine;  
<http://www.cdc.gov/nip/publications/vis/vis-ppv.pdf>.

For information on the influenza vaccines, the following site contains information on the background, types of vaccines, medical contraindications and other information:  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm>.

## **PROVISION OF IMMUNIZATIONS**

In order for a resident to exercise his or her right to make informed choices, it is important for the facility to provide the resident with education regarding the benefits and potential side effects of immunizations. Facilities are required by §483.25(n)(1)(iv) and §483.25(n)(2)(iv) to document the provision of this education and the administration or refusal of the immunization or the medical contraindication of the immunization. There may be clinical indications or other reasons that a resident may not have received immunizations. Examples may include, but are not limited to the following:

- A decision may have been made to delay vaccination for a resident because a precaution is present. According to the CDC, “under normal circumstances, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in the presence of a precaution because the benefit of protection from the vaccine outweighs the risk for an adverse reaction. The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines;”
- A resident may be in the end stages of a terminal illness and receiving care that is limited to comfort or palliative measures only. Vaccination decisions for residents in the end stages of a terminal illness should be made jointly by the physician, resident;
- A resident may have medical contraindications for live attenuated influenza vaccine (LAIV) that, according to the Centers for Disease Control and Prevention ([www.cdc.gov/flu/professionals/vaccination/shouldnotlaiiv.htm](http://www.cdc.gov/flu/professionals/vaccination/shouldnotlaiiv.htm)) include but are not limited to:
  - Persons who are 50 years of age or older, have asthma, reactive airway disease, or other chronic disorders of the pulmonary or cardiovascular systems;
  - Persons with underlying medical conditions, including such metabolic diseases such as diabetes, renal dysfunction, and hemoglobinopathies;
  - Persons with known or suspected immunodeficiency diseases or who are receiving immuno-suppressive therapies; and

- Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs;
- A resident may have already received the influenza vaccine for this season; and the pneumococcal immunization status is current;
- The resident refused the immunization.

NOTE: Inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza. Since there is a delay in developing antibodies after vaccination, the resident may develop influenza if there was exposure prior to receiving the vaccine. Coincidental respiratory disease unrelated to influenza vaccination can occur at any time after vaccination.

Following vaccination with inactivated vaccine a person may experience local reaction and/or systemic reactions. Local reactions typically include soreness at the vaccination site and body aches. Systemic reactions include fever, malaise and myalgia and persons who have had no previous exposure to the influenza virus antigens in the vaccine are most often affected.

Other reactions as identified by the CDC, which may occur immediately, presumably allergic reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) rarely are due to the influenza component of the vaccination, but probably result from hypersensitivity to other vaccine components; the majority of reactions probably are caused by residual egg protein. Persons who have had hives or swelling of the lips or tongue, or who have experienced acute respiratory distress or collapse after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons who have documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs, including those who have had occupational asthma or other allergic responses to egg protein, might also be at increased risk for allergic reactions to influenza vaccine, and consultation with a physician should be considered.

The following resource contains information on side effects of influenza vaccines:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm>

The resident's record should show vaccination administration to the resident unless the record contains documentation as to why vaccine was not administered, including but not limited to:

- Precautions necessitating delay in administering the vaccination; or
- Medical contraindications to the use of the vaccines; or
- The eligible resident refused the vaccine; or
- The resident has already been immunized.

NOTE: The influenza vaccine is given seasonally. Although the vaccines usually are representative of the influenza viruses likely to circulate during the flu season, occasionally the

vaccine may not be as closely representative. The CDC indicates that administering the vaccine during October or November is generally most effective. However, residents admitted late in the influenza season, February or March, should be offered the influenza vaccine as late season outbreaks do occur. If a resident was admitted outside the influenza season (which is October 1 through March 31), the facility is not expected to offer the influenza vaccine to the resident, but they may, at their discretion.

There should be documentation in the medical record if there is reason to believe that the pneumococcal vaccine was given previously but the date cannot be verified and this had an impact upon the decision regarding administration of the vaccine.

According to the CDC, “Pneumococcal polysaccharide vaccine generally is considered safe based on clinical experience since 1977, when the pneumococcal polysaccharide vaccine was licensed in the United States. Approximately half of persons who receive pneumococcal vaccine develop mild, local side effects (e.g., pain at the injection site, erythema, and swelling). These reactions usually persist for less than 48 hours. Moderate systemic reactions (e.g., fever and myalgia) and more severe local reactions (e.g., local induration) are rare. Intradermal administration may cause severe local reactions and is inappropriate. Severe systemic adverse effects (e.g., anaphylactic reactions) rarely have been reported after administration of pneumococcal vaccine. For more information for the pneumococcal vaccine, see <http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm>

The pneumococcal vaccine does not prevent or lessen the impact of other types of pneumonia, such as aspiration, fungal, or viral.

## **INVESTIGATIVE PROTOCOL**

### **Immunizations for Influenza and Pneumococcal Pneumonia**

#### **Objectives:**

- To determine if the facility’s immunization program has been implemented and effectively assures that residents are offered vaccines, and that residents or legal representatives receive related education;
- To determine if education regarding the benefits and potential side effects of immunization(s) was provided to the resident or legal representative each time a vaccine was offered; and
- To determine if each resident received the influenza and/or pneumococcal immunization(s) unless medically contraindicated, refused, or already immunized, or because of circumstances outside of the facility’s control, such as vaccine production delays.

#### **Sampling:**

For surveys during influenza season (October 1-March 31), follow the Procedure below for all residents who are selected for Comprehensive Reviews in Task 5C – Resident Review. If this number is below 5 residents, select additional residents from the Phase 1 Focused Review sample residents to meet the minimum number of 5 residents.

For surveys conducted outside influenza season, select 5 residents from the list the facility provided (see Task 2 – Entrance Conference) of all current residents who were in the facility during the previous influenza season. Give precedence in selection to those residents whom the survey team has selected as Phase 1 sample residents.

**Procedure:**

For all residents selected for this review, determine the following:

For the provision of Pneumococcal Pneumonia Vaccine, review all selected residents for:

- The provision of education related to the vaccine; and
- Either documentation of the administration of the vaccine; or
- If not provided, documentation as to why the vaccine was not provided, such as medical contraindications, refusal, or vaccine was already given prior to admission.

For the provision of Influenza Vaccine:

- For surveys occurring outside of influenza season, review selected residents for the provision of influenza education and immunization during the previous influenza season.
- For surveys occurring during influenza season, review all selected residents for the provision of influenza education and immunization during the current influenza season.

Review residents for:

- The provision of education for the vaccine; and
- The administration of the vaccine, or if the vaccine was not provided, the reason why the vaccine was not provided, such as medical contraindications, refusal, unavailability of the vaccine, or vaccine was already given prior to admission.

NOTE: (For surveys occurring during influenza season) - Unavailability of the influenza vaccine can be a valid reason why a facility has not implemented the influenza vaccine program, especially during the early weeks of the influenza season. It is also likely that a facility surveyed during October may not have administered the vaccine, yet. In these instances, ask the facility to demonstrate that:

- The vaccine has been ordered and the facility received either the vaccine or a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available;
- Plans are developed on how and when the vaccines are to be administered;
- Residents have been screened to determine how many and which residents are eligible and wish to receive the vaccine; and
- Education regarding immunizations has been implemented.

For surveys occurring during influenza season, review the facility's immunization program if:

- There has been no shortage or lack of availability of the vaccines and residents have not refused the vaccine, but the residents have not yet been vaccinated;
- The resident(s), have not been evaluated for vaccination status, or
- The resident(s) has not received information/education about the benefits and potential risks of the immunizations.

For all facilities, determine if the facility developed influenza and pneumococcal vaccine policies and procedures including but not limited to the following:

- The type of information/education provided to the resident prior to administration of the immunization(s);
- How the influenza vaccine program is implemented during the influenza season (October through March);
- How the pneumococcal vaccine will be provided (i.e., throughout the calendar year);
- How residents and families are educated about the benefits and risks of the vaccines;
- Processes to address issues that are-out of the facility's control such as non-availability of vaccines due to production delay or distribution problems or the presence of a precaution in a resident that may warrant a delay in vaccine;
- The identification and tracking/monitoring of a resident's vaccination status (including medical contraindications or delayed administrations);
- The location of documentation of education and administration of the vaccines; and
- How the facility determines when administration of vaccines is covered by either physician orders or physician (e.g., medical director) approved facility wide protocol.

If there are significant discrepancies between the facility's policies and procedures and the follow through for the vaccine program, ask the person responsible for implementing the procedures to explain the discrepancies.

## **Determination of Compliance (Task 6, Appendix P)**

### **Synopsis of Regulation (F334)**

The influenza and pneumococcal vaccination requirement has five aspects:

1. The resident is provided education regarding the benefits and potential side effects of the vaccinations;
2. The facility must determine if a resident is eligibility to receive the vaccinations.
3. The resident, or the resident's legal representative, has the right to refuse the vaccinations.
4. Each eligible resident is administered the influenza and pneumococcal vaccine (unless refused or contraindicated or the resident has already been immunized); and
5. The facility must document that education was provided and that the resident either received the vaccine(s) or, if not received, that the vaccines(s) was (were) refused or medically contraindicated or the resident had already been immunized.

### **Criteria for Compliance**

- Compliance with 42 CFR 483.25 (n), F334, Influenza and Pneumococcal Immunizations
  - The facility is in compliance with this requirement:
    - If each resident receives education regarding the benefits and potential side effects of the vaccine(s);
    - If each resident has been evaluated for eligibility to receive the vaccine(s);
    - If each resident is offered, unless medically contraindicated or already vaccinated, an influenza vaccine October 1 through March 31 annually, and a pneumococcal vaccine;
    - If the resident has the opportunity to refuse; and
    - If the record includes documentation that indicates, at a minimum:

- The resident was provided education regarding the benefits and potential side effects; and
- That the resident received the immunizations, refused the vaccination(s), or did not receive the vaccine(s) because of already being immunized, or as a result of a medical contraindication (including the nature of the resident's medical contraindications), unavailability, or a precaution that delayed the administration and a later date for administration has been planned.

If the facility is not in compliance with each of these aspects of the requirement, cite F334.

### **Non-compliance for F334**

After completing the investigative protocol, determine whether noncompliance with the regulation exists. Noncompliance for F334 may include, but is not limited to, one or more of the following:

- An eligible resident did not receive either the influenza and/or the pneumococcal vaccines without a valid reason.
- The facility did not evaluate to identify potential medical contraindications to the vaccines.
- The facility administered either of the vaccines to a resident who had refused them.
- The facility administered the influenza vaccine to a resident with medical contraindications, without physician involvement and/or approval.
- The facility administered the vaccine(s) to a resident who had an identified precaution, such as moderate or severe acute illness with or without fever, without physician involvement and/or approval.
- The facility administered the live attenuated influenza vaccine without physician approval to a resident who has a medical contraindication for live attenuated influenza vaccine;
- The facility failed to provide the pertinent information regarding the immunizations to the resident;
- The facility failed to document that the resident or resident's legal representative was provided education regarding the benefits and potential side effects of the influenza and, as applicable, the pneumococcal immunization; and

- The facility failed to document that the resident either received the vaccine(s) or did not receive the vaccine(s) due to medical contraindications or refusal.

### **Potential Tags for Additional Investigation**

During the investigation of F334, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Examples of some of the related requirements that may be considered when non-compliance F334 has been identified include the following:

- 42 CFR 483.20(b), F272, Comprehensive assessments
  - Review whether the resident’s comprehensive assessment documented whether the influenza and/or pneumococcal vaccines were administered in the facility, including the reason(s) why a vaccine may not have been received in the facility.
- 42 CFR 483.65, F441, Infection control program
  - Review whether the facility’s program for infection control includes the prevention of the development and transmission of disease and infections including influenza and pneumococcal pneumonia.
- 42 CFR 483.75(i)(2), F501, Medical Director
  - Determine whether the medical director has collaborated with the facility to develop policies and procedures based on current standards of practice for immunization program, including the assessment of the resident, identification of medical contraindications/precautions and emergency medical interventions in the case of allergic reactions to the vaccines.

## **V. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)**

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that non-compliance with the regulation at F334 exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F334 are as follows:

### **1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care.**

Non-compliance related to an actual or potential harm/negative outcome for F334 may include, but is not limited to:

- A resident who is not eligible to receive the vaccines is administered the vaccine and has a reaction.
- A resident who is eligible for the vaccine refuses the immunization, however, the resident is administered the vaccine.
- The facility fails to implement the immunization program and the residents experience an outbreak of influenza.

## **2. Degree of harm (actual or potential) related to the non-compliance:**

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or
- If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

## **3. The immediacy of correction required:**

Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F334. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

**NOTE:** The death or transfer of a resident who was harmed or injured as a result of facility non-compliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the non-compliance which allowed or caused the immediate jeopardy.

### **Severity Level 4 Considerations: Immediate Jeopardy to resident health or safety**

Immediate Jeopardy is a situation in which the facility's non-compliance with one or more requirements of participation:

- Has allowed/caused/resulted in, or is likely to cause/allow/result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of the facility's non-compliance that may cause or contribute to negative outcomes at severity level 4 include:

- A resident who is not eligible to receive the vaccine due to medical contraindications is administered the vaccine and experiences a life threatening reaction, such as anaphylactic shock.
- Residents who were eligible to receive vaccines did not receive them as a result of the facility's failure to have any program for vaccinating residents.

**NOTE:** If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at severity level 3.

### **Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy**

Level 3 indicates non-compliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being. Examples of negative outcomes may include, but are not limited to:

- A resident who was not eligible to receive the vaccine due to medical contraindications receives the vaccine and experiences a reaction that is not life threatening, but requires treatment.
- Because of an unwarranted delay (e.g., several weeks after it is available to the facility) in administering the influenza vaccine despite its availability, an eligible resident who has agreed to receive the influenza vaccine develops influenza.

**NOTE:** If severity level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether level 2 (no actual harm with the potential for more than minimal harm) exists.

### **Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy**

Level 2 indicates non-compliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided. Examples of outcomes may include, but are not limited to:

- An eligible resident did not receive the vaccine, but did not develop symptoms of influenza
- An eligible resident received two doses of the pneumococcal vaccine, due to a failure to document the receipt of the first dose, but did not experience any untoward reactions.

- The staff did not assess for medical contraindications prior to providing the vaccines, but there were no reactions to the vaccine.

**Severity Level 1: No actual harm with potential for minimal harm**

- The facility failed to document that information/education was provided to the resident prior to administering the immunizations.