<u>Effective November 28, 2017</u>

§483.80(b)(1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;

§483.80(b)(2) Be qualified by education, training, experience or certification;

§483.80(b)(3) Work at least part-time at the facility; and

§483.80(b)(4) Have completed specialized training in infection prevention and control.

§483.80 (c) IP participation on quality assessment and assurance committee.
The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

F883
§483.80(d) **Influenza and pneumococcal immunizations**
*§483.80(d)***(1) Influenza. The facility must develop policies and procedures to ensure that-**

- **(i) Before offering the influenza immunization, each resident or the resident's 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 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 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.**

§483.*80(d)***(2) Pneumococcal disease. The facility must develop policies and procedures** ***to*** **ensure that-**

- **(i) Before offering the pneumococcal immunization, each resident or the resident's 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 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 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.

INTENT

The intent of this regulation is to:

- Minimize the risk of residents acquiring, transmitting, or experiencing complications from influenza and pneumococcal disease by *ensuring* that each resident:
  - Is informed about the benefits and risks of immunizations; and
  - Has the opportunity to receive the influenza and pneumococcal vaccine*(s)*, unless medically contraindicated, refused or was already immunized.
- *Ensure* 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

"The Advisory Committee on Immunization Practices (ACIP)": *a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States. ACIP's recommendations stand as public health advice that will lead to a reduction in the incidence of vaccine preventable diseases and an increase in the safe use of vaccines and related biological products.* See *http://www.cdc.gov/vaccines/acip/index.html for further information.*

"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. 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 medical contraindications.

GUIDANCE

Overview

Receipt of vaccinations is essential to the health and well-being of long-term care residents. Establishing an immunization program *against influenza and pneumococcal* disease facilitates achievement of this objective. *Influenza* outbreaks place both the residents and 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.

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 of influenza and pneumococcal vaccines (administration must be based on an assessment of each resident for possible medical contraindications – see *483.30(b)(3), F711, for* physician orders for vaccinations);
- *Review of the resident's* record of vaccination and immunization status, including assessment for potential medical contraindications;
- How pertinent information *and education* will be provided to residents *or their representatives*. The facility may wish to use educational resources such as those provided by the U. S. Centers for Disease Control *and Prevention* (CDC)[69]; and
- The vaccination schedule including mechanisms for recording and monitoring for administration of both influenza and pneumococcal *vaccines in accordance with national recommendations.*[70]

***NOTE:** Review facility policies regarding the provision of vaccines in order to determine if the policies reflect current standards of practice. Refer to §483.21(b)(3)(i)- the services provided or arranged by the facility must meet professional standards of quality (F658). Also, refer to F880 for concerns with infection prevention and control.*

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 *or resident representative* with education regarding the benefits and potential side effects of immunizations. Facilities are required to document the provision of this education and the administration, 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. The resident's record should show vaccination administration unless it contains documentation as to why the vaccine was not administered, including but 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, "*in general*, 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". [70] *The benefits and risks of receiving the vaccine should be discussed with the resident or resident representative if a resident has a precaution to a vaccine. The vaccine can be administered if the benefit of the vaccine outweighs the risk, the resident or resident representative provides consent, and the resident's physician approves (refer to §483.30 Physician Services for further information on physician supervision);*
- A resident may be in the end stages of a terminal illness and receiving care that is limited to comfort or palliative measures only *and although eligible, the resident or representative has refused the vaccination(s);*

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69 Centers for Disease Control and Prevention. *Vaccine information statements.* Accessed on June 9, 2017 from https://www.cdc.gov/vaccines/hcp/vis/index.html

70 Centers for Disease Control and Prevention. (2011). General recommendations on immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR;60*(RR02), **1-60.** Accessed on June 9, 2017 from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

- A resident may have a medical contraindication *to receiving an* influenza *or pneumococcal* vaccine *such as severe allergic reaction to a vaccine component or following prior dose of vaccine;*
- The resident *or representative* refused the vaccine; or
- The resident has already been immunized.

NOTE*: For information related to current vaccine recommendations including scheduling and contraindications, refer to http://www.cdc.gov/vaccines/acip/index.html or https://www.cdc.gov/vaccines/pubs/pinkbook/chapters.html.*

NOTE*: A nursing home may encounter residents who do not have adequate documentation of vaccinations. With the* ***exception*** *of influenza vaccine and pneumococcal polysaccharide vaccine (PPSV), providers should only accept written, dated records as evidence of vaccination. Self-reported doses of influenza vaccine and PPSV are acceptable. A resident representative can report on behalf of the resident if he/she is unable to self-report and the representative has knowledge of the resident's medical care. State laws may have more stringent requirements related to documentation.*

Influenza Immunization

The influenza vaccine is given seasonally. The CDC indicates that administering the vaccine ***when it becomes available each season****, rather than date specific, (i.e., "October 1")* is most effective. *Facilities should administer the influenza vaccine when it becomes available to the facility.* Residents admitted late in the influenza season *(typically* February or March) should be offered the influenza vaccine as late season outbreaks do occur. If a resident was admitted outside the influenza season, the facility is not expected to offer the influenza vaccine to the resident, *but it may, at its discretion*.

NOTE: *Flu seasons are unpredictable in a number of ways. They can vary in different parts of the country and from season to season. While flu spreads every year, the timing, severity, and length of the season varies from one year to another.*

If there is a national shortage of influenza vaccine or other issue with availability leading to an inability to implement the influenza vaccine program, ask the facility to demonstrate that:

- *The vaccine has been ordered and the facility received 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.*

Pneumococcal Immunizations

The regulation requires that each resident is offered pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized. There should be documentation in the medical record if there is reason to believe that pneumococcal vaccine*(s)* was given previously, but the date cannot be verified, and this had an impact upon the

decision regarding administration of the vaccine*(s)*. *Facilities must follow the CDC and ACIP recommendations for vaccines.*

NOTE*: As of the date of publication of this guidance, ACIP recommends that "both 23-valent pneumococcal polysaccharide vaccine (PPSV23) and 13-valent pneumococcal conjugate vaccine (PCV13) vaccines should be administered routinely in series to all adults aged ⩾65 years."[71] ACIP explained that PPSV23 is effective in preventing invasive pneumococcal disease (IPD) but the effectiveness of PPSV23 in preventing non-bacteremic pneumococcal pneumonia has been inconsistent. 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. For more up-to-date information on timing and intervals between vaccines, please refer to ACIP vaccine recommendations located at http://www.cdc.gov/vaccines/hcp/acip-recs/index.html and https://www.cdc.gov/vaccines/schedules/hcp/index.html.*

INVESTIGATIVE SUMMARY

Surveyors must use the Infection Control Facility Task for investigating compliance with this tag. A summary of this facility task is provided below.

Sampling Procedure

Select five residents in the sample to review for the provision of influenza and pneumococcal immunizations. Give precedence in selection to those residents whom the survey team has selected as sampled residents.

Record Review

Review sampled residents' records for education on and provision, refusal, or documentation of medical contraindications for influenza and pneumococcal immunizations. As necessary, determine if the facility developed influenza and pneumococcal vaccine policies and procedures.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F883, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Develop, maintain, or follow policies and procedures for immunization of residents against influenza and pneumococcal disease in accordance with national standards of practice;*
- *Vaccinate an eligible resident with the influenza and/or the pneumococcal vaccine(s), unless the resident had previously received the vaccine, refused, or had a medical contraindication present;*
- *Allow a resident or a resident's representative to refuse either the influenza and/or the pneumococcal vaccine(s)*;

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71 Centers for Disease Control and Prevention. (2014). Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR: 63*(37); 822-825. Accessed on June 9, 2017 from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm

- *Provide and/or document the provision of pertinent information regarding the immunizations to the resident or the resident's representative such as the benefits and potential side effects of the influenza and, as applicable, the pneumococcal immunization(s); and/or*
- Document that the resident either received the *pneumococcal and influenza vaccine(s)* or did not receive the vaccine(s) due to medical contraindications, *previous vaccination,* or refusal.

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- *The facility failed to ensure that medical contraindications were identified for the influenza or pneumococcal vaccine, and administered the vaccine to a resident with identified allergies/contraindications. As a result, the resident experienced a life-threatening reaction of anaphylactic shock requiring immediate treatment and admission to the hospital.*
- *The facility failed to ensure that eligible residents received the influenza vaccines because it did not have a program for vaccinating residents. As a result, several unvaccinated residents in one unit developed influenza, with elevated temperatures, coughing, labored breathing, and required hospitalization for respiratory compromise and dehydration.*

Examples of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy include but is not limited to:

- *A resident who was not eligible to receive the influenza vaccine due to medical contraindications received the vaccine and experienced a reaction that was not serious or life-threatening (i.e., hives and dizziness). The reaction resulted in fear and anxiety that was not to the level of panic and immobilization, but required treatment.*
- *The facility failed to administer the influenza vaccine for several weeks, despite its availability. The facility failed to offer influenza immunizations to three residents who were eligible to receive the vaccine. Record review and staff interview revealed that the three residents had been admitted in the past two months, but their names were not included in the facility's monitoring log for residents who had not received the vaccine and when they had last received one. During interviews, two of the three residents stated that they had not taken "a flu shot in over a year", and one stated that he had never taken a flu shot, but all three stated they would have taken one if offered. Based on record review, two of the three residents were diagnosed with influenza with symptoms of a fever, chills, body aches, and had received treatment with an antiviral in the facility. The two residents were unable to participate in activities or leave their rooms due to the acute illness. Record review corroborated the interview information and when interviewed, staff stated they had overlooked the three residents.*

Examples of Severity Level 2 Non-Compliance: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy include but is 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 *same* pneumococcal vaccine. *The facility could have determined the resident already received the vaccine had it documented in the medical record when it was previously given by the facility. The resident did not experience any untoward reactions from the second immunization.*
- The staff did not assess *a resident* for medical contraindications prior to providing the vaccines, but there were no reactions to the vaccine.

An Example of Severity Level 1 Non-Compliance: No Actual Harm with Potential for Minimal Harm includes but is not limited to:

- *The facility failed to document that the resident was provided education on the influenza vaccine prior to administration. When interviewed, the resident stated he had received a copy of the information on influenza risks and benefits and provided the copy to the surveyor. However, the medical record did not reflect receipt of the information.*

F895

§483.85 Compliance and ethics program.
[§483.85 and all subparts will be implemented beginning November 28, 2019 (Phase 3)]

§483.85(a) Definitions.
For purposes of this section, the following definitions apply:
Compliance and ethics program means, with respect to a facility, a program of the operating organization that—

§483.85(1) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and

§483.85(2) Includes, at a minimum, the required components specified in paragraph (c) of this section.

High-level personnel means individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization.
Operating organization means the individual(s) or entity that operates a facility.

§483.85(b) General rule.
Beginning on November 28, 2019, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.

§483.85(c) Required components for all facilities.
The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components: