

(i) Systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events;

(ii) Documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities; and

(iii) Other documentation considered necessary by a State or Federal surveyor in assessing compliance.

(i) Sanctions. Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

33. Newly redesignated §483.80 is revised to read as follows:

**§483.80 Infection control.**

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

(a) Infection prevention and control program. The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to §483.75(e) and following accepted national standards;

(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:

(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;

(ii) When and to whom possible incidents of communicable disease or infections should be reported;

(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;

(iv) When isolation should be used for a resident;

(v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and

(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact,

(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

(b) Infection prevention and control officer. The facility must designate one individual as the infection prevention and control officer (IPCO) for whom the IPCP at that facility is a major responsibility. The IPCO must:

(1) Be a clinician who works at least part-time at the facility, and

(2) Have specialized training in infection prevention and control beyond their initial professional degree.

(c) IPCO participation on quality assessment and assurance committee. The person designated as the IPCO 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.

(d) Influenza and pneumococcal immunizations — (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.

(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.

(e) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

(f) Annual review. The facility will conduct an annual review of its IPCP and update their program, as necessary.

34. Section 483.85 is added to read as follows:

**§483.85 Compliance and ethics program.**

(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--

(i) 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

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