

Centers for Medicare & Medicaid Services, HHS

§ 483.80

such committee with the requirements of this section.

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

[81 FR 68867, Oct. 4, 2016, as amended at 82 FR 32259, July 13, 2017]

§ 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 § 483.70(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 and how isolation should be used for a resident; including but not limited to:

(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and

(B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.

(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 preventionist.* The facility must designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's IPCP. The IP must:

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

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

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

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

(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.

(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.

(g) *COVID-19 reporting.* The facility must—

(1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to—

(i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;

(ii) Total deaths and COVID-19 deaths among residents and staff;

(iii) Personal protective equipment and hand hygiene supplies in the facility;

(iv) Ventilator capacity and supplies in the facility;

(v) Resident beds and census;

(vi) Access to COVID-19 testing while the resident is in the facility;

(vii) Staffing shortages; and

(viii) Other information specified by the Secretary.

(2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—

(i) Not include personally identifiable information;

(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and

(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

(h) *COVID-19 Testing.* The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

- (i) Testing frequency;
- (ii) The identification of any individual specified in this paragraph diagnosed with COVID-19 in the facility;
- (iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;
- (iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;
- (v) The response time for test results; and
- (vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

- (i) Document that testing was completed and the results of each staff test; and
- (ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

[81 FR 68868, Oct. 4, 2016, as amended at 85 FR 27627, May 8, 2020; 85 FR 54873, Sept. 2, 2020]

§ 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—

(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

(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.

(b) *General rule.* Beginning 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.

(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:

(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.

(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance