

Administrative practice and procedure, Grant programs—health, Health facilities, Home infusion therapy, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural and urban areas.

42 CFR Part 494

Diseases, Health facilities, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 416-- AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

2. Amend § 416.51 by adding paragraph (c) to read as follows:

§ 416.51 Conditions for coverage—Infection control.

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(c) *Standard: COVID-19 vaccination of staff.* The ASC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following center staff, who provide any care, treatment, or other services for the center and/or its patients:

- (i) Center employees;
- (ii) Licensed practitioners;
- (iii) Students, trainees, and volunteers; and
- (iv) Individuals who provide care, treatment, or other services for the center and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following center staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section; and

- (ii) Staff who provide support services for the center that are performed exclusively outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine, prior to staff providing any care, treatment, or other services for the center and/or its patients;

- (ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

- (iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for

COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the center has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized or licensed COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the center's COVID-19 vaccination requirements based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal

antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 418—HOSPICE CARE

3. The authority citation for part 418 continues to read as follow:

Authority: 42 U.S.C. 1302 and 1395hh.

4. Amend § 418.60 by adding paragraph (d) to read as follows:

§ 418.60 Condition of participation: Infection control.

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(d) *Standard: COVID-19 Vaccination of facility staff.* The hospice must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following hospice staff, who provide any care, treatment, or other services for the hospice and/or its patients:

(i) Hospice employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the hospice and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following hospice staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where hospice services are provided to patients and who do not have any direct contact