

# NOTICE OF UPDATE

Please note the following change to *Accreditation Requirements for Ambulatory Surgery Center*, 2021 edition.

Standard **05.04.01 COVID-19 Vaccination of Staff** has been established per CMS requirements. The change becomes effective for surveys beginning January 27, 2022, in states *except*: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Utah, West Virginia and Wyoming where surveys for compliance will begin on February 14, 2022. In Texas, surveys for compliance will begin February 22, 2022.

The Standard, Required Elements, and Scoring Procedure are presented below in entirety.

## Standard 05.04.01 Current 12.02.01 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 two 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 #1; 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 #1.
3. The policies and procedures must include, at a minimum, the following components:
  - i. A process for ensuring all staff specified in paragraph #1 (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 #1 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 #1;
  - 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 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.

§416.51(c), §416.51(c)(1), §416.51(c)(1)(i), §416.51(c)(1)(ii), §416.51(c)(1)(iii), §416.51(c)(2)(i), §416.51(c)(2)(ii), §416.51(c)(3), §416.51(c)(3)(i), §416.51(c)(3)(ii), §416.51(c)(3)(iii), §416.51(c)(3)(iv), §416.51(c)(3)(v), §416.51(c)(3)(vi), §416.51(c)(3)(vii), §416.51(c)(3)(viii), §416.51(c)(3)(viii)(A), §416.51(c)(3)(viii)(B), §416.51(c)(3)(ix), §416.51(c)(3)(x)

**REQUIRED ELEMENTS/ADDITIONAL INFORMATION**

ASCs must have a process for ensuring all staff have received at least a primary vaccine series prior to providing any care, treatment, or other services for the facility and/or its patients.

**POLICIES AND PROCEDURES**

Policies and procedures address, at a minimum:

- Obtaining and documenting each staff member's vaccination status.
- The process by which staff may request an exemption from COVID-19 vaccination based on an applicable federal law; this process identifies:
  - » How an exemption is requested, and
  - » To whom the request must be made.
- Precautions that are intended to mitigate the spread of COVID-19 that must be adhered to by staff who are not yet fully vaccinated, or who have been granted an exemption or accommodation as authorized by law, or who have a temporary delay.
- Employed or contracted staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) who may not be subject to the vaccination requirements.
  - » Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination.
- Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

The ASCs must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination requirements by the ASCs have:
  - » Documented information that includes the type of exemption and supporting documentation, such as the ASC's determination of the request and any accommodations.
  - » Medical exemption documentation specifying:
    - Which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member.
    - The recognized clinical reasons for the contraindication.
    - A statement recommending that the staff member be exempted from the ASC's COVID-19 vaccination requirements based on the medical contraindications.
    - Be signed and stated by a licensed practitioner who is not the same individual requesting the exemption.
- Staff for whom COVID-19 vaccination must be temporarily delayed and when the identified staff can safely resume their vaccination.

The tracking method and documentation must clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

### **MEDICAL EXEMPTIONS**

Certain allergies or recognized medical conditions, may provide grounds for exemption.

- In general, the CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within four hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.
  - » NOTE: The CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical precautions and considerations, such as individuals with acute illness secondary to COVID-19 illness, and individuals who received monoclonal antibodies, or convalescent plasma for COVID-19 treatment.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable state and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

### **ACCOMMODATIONS OF UNVACCINATED STAFF WITH A QUALIFYING EXEMPTION**

While accommodations for individual unvaccinated staff could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. Staff who have been granted an exemption to COVID-19 vaccination requirements must adhere to the organization's policies for unvaccinated healthcare personnel.

### **NON-MEDICAL EXEMPTIONS, INCLUDING RELIGIOUS EXEMPTIONS**

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each ASC's policies and procedures.

### **CONTINGENCY PLAN**

The ASC must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Organizations should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine.

Contingency plans include actions that the ASC would take:

- For staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions.
- When staff have indicated that they will not get vaccinated and do not qualify for an exemption.
- If the deadline for vaccination is not met.

## SURVEY PROCEDURE

### Interview and Document Review

Verify:

- Policies and procedures address each required element.
- A list of all staff and their vaccine status is maintained.
- Vaccination status, including booster shots, is tracked and documented and includes all required elements.
- Vaccination exemptions are tracked and documented and include all required elements.
- Contingency plans address unvaccinated staff and those staff not yet fully vaccinated.

Review:

- A sample of staff records to confirm appropriate documentation is maintained for (as applicable):
  - » Direct care staff (vaccinated and unvaccinated).
    - For unvaccinated staff, determine if education was provided and vaccination offered and/or if an exemption is documented.
  - » Contracted staff.
  - » Direct care staff with an exemption.

Interview:

- Staff to confirm vaccination status.