DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-09-ALL
Expired 10/26/22

DATE: **January 14, 2022**

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Memorandum Summary

Effective 10-26-22, this memo has been superseded by QSO-23-02-All: Revised Guidance for Staff Vaccination Requirements.

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum specifically applies to the following states: 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.
- The guidance in this memorandum does not apply to the following state at this time: Texas. **Surveyors in Texas should not undertake any efforts to implement or enforce the IFC.**
- States that are not identified above are expected to continue under the timeframes and parameters identified in the December 28, 2021 memorandum (QSO-22-07-ALL).

Background

Since the beginning of the Public Health Emergency, CMS and the Centers for Disease Control and Prevention (CDC) data show as of mid-October, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalization, and 720,000 COVID-19 deaths have been reported. The

CDC has reported that COVID-19 vaccines are safe and effective at preventing severe illness from COVID-19 and limiting the spread of the virus that causes it. On December 11, 2020, the Advisory Committee in Immunization Practices (ACIP) recommended, as interim guidance, that both 1) health care personnel, and 2) residents of long-term care (LTC) facilities be offered COVID-19 vaccine in the initial phase of the vaccination program. To support this

recommendation, on May 13, 2021, CMS published an interim final rule with comment period (IFC), entitled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff" (86 FR 26306). Also, CMS released guidance for surveyors and LTC facilities in the CMS memo, QSO-21-19-NH, Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff. This rule required all certified LTC facilities (i.e., nursing homes) to educate all residents and staff on the benefits and potential side effects associated with the COVID-19 vaccine, and offer the vaccine.

The regulation was intended to help increase vaccination rates among nursing home residents and staff to reduce the risk of infection and disease associated with COVID-19. Approximately two months after the publication of the rule, about 80 percent of nursing home residents were vaccinated. However, during that same time, roughly 60% of nursing home staff were vaccinated.[1] Therefore, more actions are warranted to increase vaccination rates among staff.

On August 18, 2021, CMS announced that it would be issuing a regulation that all nursing home staff would have to be vaccinated against COVID-19 as a requirement for LTC facilities participating with the Medicare and Medicaid programs. Subsequently, on September 9, 2021, CMS announced that this requirement would be extended to nearly all Medicare and Medicaid-certified providers and suppliers. These actions aim to support increasing vaccination rates among staff working in all facilities, providers, and certified suppliers that participate in Medicare and Medicaid.

Discussion

On November 5, 2021, CMS published an IFC with comment period (86 FR 61555), entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," revising the infection control requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of patients and staff during the COVID-19 public health emergency. The COVID-19 vaccination requirements and policies and procedures required by this IFC must comply with applicable federal non-discrimination and civil rights laws and protections, including providing reasonable accommodations to individuals who are legally entitled to them because they have a disability or sincerely held religious beliefs, practices, or observations that conflict with the vaccination requirement. More information on federal non-discrimination and civil rights laws is available here: https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

Vaccination Enforcement– Surveying for Compliance

Medicare and Medicaid-certified facilities are expected to comply with all regulatory requirements, and CMS has a variety of established enforcement remedies. For nursing homes, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payments, and—as a final measure—termination of participation from the Medicare and Medicaid programs. The sole enforcement remedy for non-compliance for hospitals and certain other acute and continuing care providers is termination; however, CMS's primary goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

[1] COVID-19 Nursing Home Data - Centers for Medicare & Medicaid Services Data (cms.gov)

CMS expects all providers' and suppliers' staff to have received the appropriate number of doses by the timeframes specified in the QSO-22-07 unless exempted as required by law, or delayed as recommended by CDC. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.** Non-compliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. Consistent with CMS's existing enforcement processes, this guidance will help surveyors determine the severity of a noncompliance deficiency finding at a facility when assigning a citation level. These enforcement action thresholds are as follows:

Within 30 days after issuance of this memorandum[2], if a facility demonstrates that:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
- 100% of staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice[3] of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 60 days after the issuance of this memorandum[4], if the facility demonstrates that:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple-dose vaccine series, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is non-**

[2] If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.
[3] This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) federal tag.
[4] If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

compliant under the rule. The facility will receive notice[5] of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 90 days and thereafter following issuance of this memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Federal, state, Accreditation Organization, and CMS-contracted surveyors will begin surveying for compliance with these requirements as part of initial certification, standard recertification or reaccreditation, and complaint surveys 30 days following the issuance of this memorandum. Additional information and expectations for compliance can be found at the provider-specific guidance attached to this memorandum.

Provider-Specific Guidance:

Guidance specific to provider types and certified suppliers is provided in the following attachments. The provider-specific guidance should be used in conjunction with the information in this memo.

- Attachment A: LTC Facilities (nursing homes)
- Attachment B: ASC
- Attachment C: Hospice
- Attachment D: Hospitals
- Attachment E: PRTF
- Attachment F: ICF/IID
- Attachment G: Home Health Agencies
- Attachment H: CORF
- Attachment I: CAH
- Attachment J: OPT
- Attachment K: CMHC
- Attachment L: HIT
- Attachment M: RHC/FQHC
- Attachment N: ESRD Facilities

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during a survey.

Contact:
DNH_TriageTeam@cms.hhs.gov for questions related to nursing homes;

[5] This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) tag.

QSOG_Emergencyprep@cms.hhs.gov for question related to acute and continuing care providers.

Effective Date: This policy should be communicated with all survey and certification staff, their managers, and the State/CMS Location training coordinators immediately. The effective dates of the specific actions are specified above.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

cc: Survey and Operations Group Management
Attachments: A through N