### DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



# Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

**Ref: QSO-23-02-ALL** 

**DATE:** October 26, 2022

**TO:** State Survey Agency Directors

**FROM:** Directors

Quality, Safety & Oversight Group (QSOG) and Survey & Operations

Group (SOG)

**SUBJECT:** Revised Guidance for Staff Vaccination Requirements

#### **Memorandum Summary**

- CMS is committed to taking critical steps to protect vulnerable individuals to ensure America's health care facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 5, 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 revising its guidance and survey procedures for all provider types related to assessing and maintaining compliance with the staff vaccination regulatory requirements.
- This memorandum replaces memoranda QSO 22-07-ALL Revised, and QSO 22-09-ALL Revised, and QSO 22-11-ALL Revised to consolidate the information into a single memorandum. The guidance in this memorandum <u>applies</u> to all states.

#### **Background**

On November 5, 2021, CMS issued an interim final rule with comment period (86 FR 61555) titled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (also referred herein as the "staff vaccination requirement"). This IFC revised the requirements to establish COVID-19 vaccination requirements for staff at applicable Medicare and Medicaid-certified providers and suppliers.

The staff vaccination requirement for all CMS-certified providers and suppliers has been enforced in all states since February 20, 2022. To date, most providers and suppliers surveyed by states have been found to be in substantial compliance with this requirement.

Hospitalizations and deaths from COVID-19 currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local,

and private partners have done to get over 226 million people vaccinated and over 111 million boosted.

### **Discussion**

CMS is replacing QSO memoranda 22-07-ALL Revised, 22-09-ALL Revised, and 22-11-ALL Revised and is revising the interpretive guidance for all provider types found in Attachments A through N. The revisions address frequency of review of the Staff Vaccination requirements, as well as Immediate Jeopardy, Condition-level and actual harm determinations to ensure that deficiency citations recognize good faith efforts by providers/suppliers.

### **Vaccination Enforcement**

Medicare and Medicaid-certified facilities are expected to comply with all applicable 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 noncompliance 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.

CMS expects all providers' and suppliers' staff to have received the appropriate number of doses of the primary vaccine series unless exempted as required by law, or delayed as recommended by CDC. Facility staff vaccination rates under 100% constitute noncompliance under the rule. Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. For example, a facility that is noncompliant and has implemented a plan to achieve compliance would not be subject to an enforcement action.

### **Review of Staff Vaccination Requirements**

While Federal, State agencies (SAs), Accrediting Organization (AOs), and CMS-contracted surveyors may expand any survey to include staff vaccination requirement compliance review, SAs and AOs will only be expected to perform compliance reviews of the staff vaccination requirements as part of initial certification, standard recertification or reaccreditation surveys, and in response to specific complaint allegations related to the staff vaccination requirements. Surveyors may modify the staff vaccination compliance review if the provider/supplier was determined to be in substantial compliance with this requirement within the previous six weeks. 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 has been updated, and revised for assigning severity at Immediate Jeopardy, Harm, and Condition levels to align with <u>OSO-22-17-ALL</u>. State Survey Agencies should reach out to their CMS Location if they are considering citing vaccine requirements at immediate jeopardy, condition or actual harm levels.

- 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:**

<u>DNH\_TriageTeam@cms.hhs.gov</u> for questions related to nursing homes;

<u>QSOG\_Emergencyprep@cms.hhs.gov</u> 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.

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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