



Issued: December 30, 2021

On November 4, 2021, the Centers for Medicare and Medicaid Services (CMS) issued an emergency regulation entitled “CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule” (CMS rule) which requires certain employers who are certified under the Medicare and Medicaid programs to issue a policy requiring all employees to be vaccinated against COVID-19. (See <https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination>.)

On December 1, 2021, after two federal district courts instituted preliminary injunctions that barred enforcement of the CMS rule in all states, the District of Columbia and the US Territories, CMS issued guidance to State Survey Agency Directors that “while these preliminary injunctions are in effect, surveyors must not survey providers for compliance with the requirements of the [CMS rule]” (see <https://www.cms.gov/files/document/qso-22-04-all.pdf>). Then, on December 15, 2021, the United States Court of Appeals for the Fifth Circuit lifted the portion of the preliminary injunction that barred enforcement of the CMS rule in several states, including the State of New York.

On December 28, 2021, CMS issued a new memorandum (QSO-22-07) to State Survey Agency Directors with supporting provider-specific attachments, applicable to New York providers, which announced new time frames to be used by regulatory surveyors to assess compliance with the CMS rule.

This document updates guidance on the applicability of the CMS rule to the OPWDD service system. **It is not intended to supplant the CMS rule and providers should conduct their own review of the CMS rule and the QSO-22-07 memorandum and attachments.**¹

1. CMS Rule’s Applicability to Providers and Suppliers:

The CMS rule applies to covered staff at specific health care facilities that are certified Medicare and Medicaid providers. In the OPWDD service system this would include the following facilities:

- Intermediate Care Facilities (ICFs), including OPWDD’s developmental centers;
- Specialty Hospitals; and
- Article 16 Clinics to the extent the facility is enrolled in Medicare under 42 CFR 485.725.

The CMS rule **does not apply** to the following facilities and services in the OPWDD service system:

- Home and Community-Based Services (HCBS) Facilities or services, such as Individualized Residential Alternatives (IRAs)/Residential Habilitation, Family Care, Day Habilitation, Community Habilitation, Supported Employment, and other HCBS programs, unless the facility is co-located with either an Article 16 clinic, Specialty Hospital, or ICF and the two entities share communal space or

¹ The CMS website containing the memorandum and all provider-specific attachments may be accessed here: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/guidance-interim-final-rule-medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-0>. Providers should pay particular attention to the lead memorandum and Attachments F and J, which apply to OPWDD providers operating covered facilities.

employees;

- CCO/Health Homes;
- CSIDD;
- IPSIDD (unless location of service delivery is an Article 16 clinic subject to the rule);
- Programs that are 100% State-funded.

2. Applicability to Staff at Covered Facilities:

The CMS rule applies to staff at the covered facilities whether or not they work with individuals or the public. The rule includes employees, licensed practitioners, students, trainees and volunteers. It applies to employees who routinely provide services for the facility under contract or other arrangements. The rule applies to employees who provide services off-site and to those who telecommute but who occasionally go into work. Any employee who performs duties at any site or who may come into contact with anyone at the facility must be fully vaccinated as set forth in this rule.

The CMS rule **does not apply** to the following staff:

- Staff who are full-time telecommuters and who do not come into contact with other employees or individuals receiving services, such as those providing full-time telehealth services or payroll services; and
- Infrequent non-healthcare service providers, such as those who provide “one-off” services (e.g., repair services, delivery).
- Those who have received a reasonable accommodation under applicable federal standards (e.g., ADA or Title VII).

3. Timing of Compliance:

Pursuant to CMS Memorandum QSO-22-07, by **January 27, 2022**, all covered employers must develop and implement policies that ensure that 100% of covered staff are vaccinated against COVID-19 (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) pursuant to the following timeframes:

- By **January 27, 2022**, staff must have received at least one dose of COVID-19 vaccine (i.e. a single dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose 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.
- Facilities who have less than 100% of all staff in compliance by January 27, 2022, may receive notice 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.
- By **February 26, 2022** staff must 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.
- Facilities with less than 100% of all staff in compliance by February 26, 2022 may receive a notice 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.
- By **March 28, 2022**, all facilities must be in full compliance with the 100% vaccination standard.

Facilities that fail to meet any of these parameters within the identified timeframes are considered out of compliance with the rule and 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.)

Please note that in addition to the vaccination timelines, the provider must have policies in place that include process for ensuring all covered staff have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment, or other services for the facility and/or its service recipients. The required policies are further described in paragraph 6 below.

4. Proof of Vaccination Status:

Providers and suppliers must track employee vaccination status, as well as any booster doses (including the specific vaccine booster received and the date of administration), and keep such records confidential. Examples of acceptable forms of proof of vaccination include:

- CDC COVID-19 vaccination record card (or a legible photo of the card).
- Documentation of vaccination from a health care provider or electronic health record.
- State immunization information system record.
- Excelsior Pass may also be accepted.

5. No Testing Option:

There is no “test-out” option for covered employees under the CMS rule. Staff who have previously had COVID or who have COVID antibodies are not exempt from this rule.

6. Procedures:

By **January 27, 2022**, providers must develop and implement policies and procedures, described in further detail in the memorandum, which include:

- A process for ensuring that all staff (except for those staff who have pending requests for, or who have been granted exemptions to the vaccination requirements of the rule, or whose vaccination has been temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) receive the required vaccination doses within the time frames set forth in paragraph 3 above.
- A process by which staff may request an exemption from the COVID-19 vaccination requirements based upon applicable Federal Law.
- A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the COVID-19 vaccination requirements.
- A process to ensure that all staff seeking a medical exemption provide documentation from a licensed practitioner who is not the individual requesting the exemption and is acting within their respective scope of practice based on applicable state and local laws. Such documentation must contain all information specifying which COVID-19 vaccinations are clinically inadvisable, the recognized reason for such contraindication, and a statement from the authenticating practitioner recommending that the staff member be exempted from the facility’s COVID-19 vaccination requirements based on the recognized clinical contraindications.
- A process to track and secure documentation of the vaccination status of staff for whom COVID-19 vaccinations must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.

- A contingency plan and a process to mitigate the transmission and spread of COVID for staff who are not fully vaccinated, including those who have received a reasonable accommodation or for whom vaccination must be temporarily delayed due to clinical precautions. CMS has included more information about contingency plans and mitigation precautions in Attachments F and J to QSO-22-07.

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7. Enforcement:

CMS will enforce this rule through federal, state, Accreditation Organization, and CMS-contracted surveyors who will review the providers' records and may conduct interviews. CMS will begin surveying for compliance on or about January 27, 2022. Non-compliant providers will be given an opportunity to become compliant as described above but may face civil monetary penalties, denial of new admissions to the program, and termination from the Medicare and Medicaid programs if they continue to be out of compliance or are not fully compliant by March 28, 2022.

This guidance is based upon current information and is subject to change. Providers should closely review all CMS guidance issued.