Medicare and Medicaid Programs: Omnibus COVID-19 Health Care Staff Vaccination; CMS-3415-IFC Interim Final Rule Summary

On November 5, 2021, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register (FR) an interim final rule with comment period (IFC): Medicare and Medicaid Programs: Omnibus COVID-19 Health Care Staff Vaccination (86 FR 61555). The IFC revises the conditions of participation for Medicare- and Medicaid-certified providers to establish COVID-19 vaccination requirements applicable to staff. CMS uses its broad statutory authority to establish health and safety regulations for Medicare- and Medicaid-certified providers to establish vaccination requirements for the following types of facilities and services:

- Ambulatory Surgical Centers (ASCs)
- Hospices
- Psychiatric Residential Treatment Facilities (PRTFs)
- Programs of All-Inclusive Care for the Elderly (PACE)
- Hospitals
- Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs)
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Home Health Agencies (HHAs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals (CAHs)
- Clinics, Rehabilitation Agencies, and Public Health Agencies as providers of outpatient physical therapy and speech-language pathology services (referred to as "Organizations")
- Community Mental Health Centers (CMHCs)
- Home Infusion Therapy (HIT) suppliers
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs)
- End-Stage Renal Disease (ESRD) Facilities

The IFC is accompanied by publication of a frequently asked questions document.[1] **Comments are due on January 4, 2022.**

I. Background

CMS describes the need for the regulations to respond to the public health emergency (PHE). It identifies the prior actions both internationally and within the U.S. to identify, declare, and respond to the pandemic including declarations that a national emergency exists. Most recently, the determination that a PHE for COVID-19 exists was extended for a period of 90 days on October 18, 2021.

CMS reviews the impact of COVID-19 on mortality and morbidity of the U.S. population citing numerous research studies. It reviews evidence of post-acute long-term consequences of COVID-19 and the possibility of mortality increases beyond those directly attributed to COVID-

[1] CMS Omnibus Staff Vax Requirements - External FAQ (508 Compliant)

19. It provides evidence of the disproportionate burden of COVID-19 on minority and disadvantaged populations.

The evidence of the impact of the vaccines as well as other infection prevention and control practices on preventing morbidity and mortality associated with COVID-19 are reviewed including evidence originating from the experiences of health care facilities. CMS describes the threats that unvaccinated health care staff pose to patients. In addition to transmitting COVID-19, CMS is concerned that fear of transmission can jeopardize access to necessary care because people fearing transmission from unvaccinated health care workers will forgo necessary care and because staff shortages could be exacerbated by absenteeism due to COVID-19 exposure or illness. This problem has been a particular concern for hospitals seeking to place patients in post-acute facilities and nursing homes that have had to limit new admissions because of staffing shortages.

CMS is concerned about the threat of illness or death among healthcare staff. CMS cites data showing that the number of cases among staff of healthcare facilities has been rising and notes that vaccination rates in some facilities in certain regions are low. For example, vaccinations rates for LTC facility, hospital, and ESRD staff are at 67 percent, 64 percent and 60 percent respectively. In addition, CMS is concerned that the risks associated with unvaccinated health staff may also disproportionately impact communities experiencing social risk factors and other populations at risk.

CMS describes its responsibility to protect the health and safety of individuals providing and receiving care and services at or from certain Medicare- and Medicaid-certified providers and suppliers, CMS uses it statutory authority to establish health and safety regulations and in some cases infection prevention and control procedures to require staff vaccinations for COVID-19 in these settings.

CMS reviews its regulatory response to the COVID-19 PHE to date including exercising regulatory flexibilities for healthcare providers via waivers and prior rulemaking. CMS has so far issued five IFCs to help contain the spread of the virus. CMS reviews those rules as well as Occupational Safety and Health Administration (OSHA) rulemaking which established standards to protect health care and health care support service workers from occupational exposure to COVID-19. It notes that this IFC builds upon the OSHA rule.

CMS reviews the process which brought the COVID-19 vaccines to the public. It identifies vaccines currently authorized for use in the U.S. and describes a complete vaccination series for each according to CDC guidance to date. The IFC requires Medicare- and Medicaid-certified providers and suppliers to ensure that staff are fully vaccinated for COVID-19, unless the individual is exempted. Consistent with CDC guidance, staff are considered to be fully vaccinated if it has been 2 or more weeks since they completed a primary vaccination series for COVID-19. A primary vaccination series is described as having received a single-dose vaccine or all doses of a multi-dose vaccine. For purposes of the IFC, third doses and booster doses are not required. CMS notes that these definitions of fully vaccinated are consistent with OSHA definitions.

With respect to individuals vaccinated outside of the U.S. or who have been vaccinated as part of a clinical trial, CMS defers to CDC guidance available at Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC.

Additional issues, such as intervals between doses, repeat doses, booster doses, and the safety and efficacy of the approved vaccines is reviewed. CMS also reviews the stakeholder interest in vaccination requirements for health care workers. It cites the growing number of professional societies and associations calling for such requirements and describes the experience of a number of large health systems that have already implemented vaccine requirements.

CMS states that this regulation preempts inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers, consistent with the Supremacy Clause of the U.S. Constitution.

II. Provisions of the IFC

A. Facilities Impacted

Under the requirements in the IFC, Medicare- and Medicaid-certified providers and suppliers must ensure that all applicable staff are vaccinated for COVID-19. The providers and suppliers impacted by the rule and the section of regulations in which the new requirements are codified are listed below.

Provider/Supplier	Section Amended Title 42 of the Code of Federal Regulations
Ambulatory Surgical Centers (ASCs)	§ 416.51
Hospices	§ 418.60
Psychiatric Residential Treatment Facilities (PRTFs)	§ 441.151
Programs of All-Inclusive Care for the Elderly (PACE)	§ 460.74
Hospitals	§ 482.42
Long Term Care (LTC) Facilities	§ 483.80
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	§ 483.430
Home Health Agencies (HHAs)	§ 484.70
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	§§ 485.58 and 485.70
Critical Access Hospitals (CAHs)	§ 485.640
Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (Organizations)	§ 485.725
Community Mental Health Centers (CMHCs)	§ 485.904
Home Infusion Therapy (HIT) Suppliers	§ 486.525
Rural Health Clinics (RHCs)/ Federally Qualified Health Centers (FQHCs)	§ 491.8
End-Stage Renal Disease (ESRD) Facilities	§ 494.30

The IFC applies only to Medicare- and Medicaid-certified facilities. Its requirements are not applicable to:

- Religious Nonmedical Health Care Institutions (RNHCIs), Organ Procurement Organizations (OPOs), and Portable X-Ray Suppliers;

- Assisted Living Facilities, Group Homes or Medicaid Home and Community Based Services. CMS does not have regulatory authority over those types of facilities; and
- Physician's offices. Because they are not subject to CMS health and safety regulations, they are not subject to the IFC's requirements.

B. Staff Subject to COVID-19 Vaccination Requirements

The requirements of this IFC apply to all current staff and new staff who provide any care, treatment or other services for the facility and/or its patients. That group includes facility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement.

CMS notes that the requirements apply to all staff that interact with other staff, patients, residents, clients or PACE program participants in any location, beyond those that physically enter facilities, clinics, homes or other sites of care. It includes individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, social workers, and portable x-ray suppliers who provide such health care services at a facility.

It does not apply to individuals who provide services 100 percent remotely such as telehealth providers or those providing fully remote payroll services nor to individuals who infrequently provide ad hoc non-health care services (such as annual elevator inspections), or services that are performed exclusively off-site, not at a site adjacent to any site of patient care (such as accounting services). This exemption is for individuals who may infrequently enter a facility or site of care for specific limited purposes and for a limited amount of time, for example delivery and repair personnel. CMS notes that facilities may choose to extend their policies and procedures to those individuals, however.

C. When Staff are Considered Fully Vaccinated

Staff are considered to be fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19 or who have who have completed the primary series for the vaccine by the Phase 2 implementation date (even if they have not yet completed the 14-day waiting period required for full vaccination). The completion of a primary vaccination series for COVID-19 is defined as the administration of a single-dose vaccine (such as the Janssen (Johnson & Johnson) COVID-19 Vaccine), or the administration of all required doses of a multi-dose vaccine (such as the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty Vaccine) or the Moderna COVID-19 Vaccine).

Staff who receive vaccines listed by the World Health Organization (WHO) for emergency use that are not approved or authorized by the FDA or as a part of a clinical trial are also considered to have completed the vaccination series in accordance with CDC guidelines.

At this time, CMS is not requiring that individuals receive boosters to be considered to be fully vaccinated under these rules.

D. Infection Prevention and Control

All providers and suppliers must have a process to ensure additional precautions are in place to mitigate the transmission and spread of COVID-19 for those not fully vaccinated. Providers that do not have infection prevention and control requirements (PRTFs, RHCs/FQHCs, and HIT suppliers) are required to have a process for ensuring that they follow nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19. This process must include the implementation of additional precautions for all staff who are not fully vaccinated.

E. Documentation of Staff Vaccinations

The IFC requires providers and suppliers subject to the rules to track and securely document the vaccination status of each staff member and to document vaccine exemption requests and outcomes. Records must be confidential and stored separately from an employer's personnel files. Acceptable examples of places to store such documentation include immunization records or health information files. Acceptable proof of vaccination includes CDC vaccination record cards, documentation of vaccination from a health care provider or electronic record or a state immunization information system card. CDC provides a staff vaccination tracking tool that may be used. It is available at https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.

F. Vaccine Exemptions

Under the IFC, providers and suppliers are required to establish and implement a process by which staff may request an exemption from the vaccination requirements. Grounds for exemption may include certain allergies; recognized medical conditions; or religious beliefs, observances, or practices.

The CDC provides information on clinical contraindications to receiving a COVID-19 vaccine: Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, at https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical- considerations.pdf.

The Americans with Disability Act and Title VII of the Civil Rights Act of 1964 may require accommodations to be provided for some individual staff members. Requests for exemptions based on those laws must be documented and evaluated in accordance with those laws as well as with the facility's policies and procedures.

Requests for medical exemptions must be documented, signed and dated by a licensed practitioner acting within their scope of practice.

In granting an exemption to vaccination requirements, employers must minimize the risk of transmission of COVID-19 to at-risk individuals and protect employees from retaliation. The following additional resources are provided for reference: The Equal Employment Opportunity Commission's website at What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws | U.S. Equal Employment Opportunity Commission (eeoc.gov); The Safer Federal Workforce Task Force's template for exceptions: Template -

Request for a Medical Exception to the Covid-19 Vaccination Requirement (saferfederalworkforce.gov); and Request For A Religious Exception To The Covid-19 Vaccination Requirement - Template (saferfederalworkforce.gov).

G. Planning

CMS is requiring providers and suppliers to have contingency plans for staff who are not fully vaccinated to ensure that they will soon be vaccinated and will not provide care, treatment, or other services for the provider or its patients until they have completed the primary vaccination series or at least have had the first dose of a multi-dose vaccine for COVID-19. Plans should address the safe provision of services by individuals who have requested exemptions while the exemption is being considered and for others experiencing a delay because of clinical considerations.

F. Implementation Dates

By December 6, 2021: Phase 1 must be implemented. Phase 1 requires that all staff will have received at a minimum the first dose of the primary series or a single dose vaccine or have requested, or have been given, an exemption. In addition, all facilities must have reviewed, modified, and implemented policies and procedures that conform with the requirements of the IFC.

By January 4, 2021: Phase 2 must be implemented. Phase 2 requires that all applicable staff are fully vaccinated for COVID-19 exempt for those granted exemptions. Although an individual is not considered fully vaccinated until 14 days (2 weeks) after the final dose, staff who have received the final dose of a primary vaccination series by the Phase 2 effective date are considered to have met the individual vaccination requirements, even if they have not yet completed the 14-day waiting period.

CMS notes that there is no sunset clause for these requirements nor is there a link to the timeline for the PHE declaration even though the IFC is being issued in response to the PHE for COVID-19. CMS states that it expects that the procedures will remain relevant beyond the end of the formal PHE and depending on the course of the pandemic, they may become permanent requirements for facilities.

G. Enforcement

CMS expects to issue additional interpretive guidelines, which may include survey procedures, following publication of this IFC. State surveyors will regularly review compliance with the requirements during standard recertification surveys as well as compliance surveys, will be instructed to conduct interviews with staff to verify vaccination status, and will review entities' policies and procedures.

Surveyors may cite providers and suppliers when noncompliance is identified. Those cited for noncompliance may be subject to enforcement remedies imposed by CMS depending on the level of noncompliance and the remedies available under Federal law (for example, civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid

provider agreement). CMS will closely monitor the status of staff vaccination rates, provider compliance, and any other potential risks to patient, resident, client, and PACE program participant health and safety.

III. Waiver of Proposed Rulemaking

Under the Administrative Procedure Act (APA), CMS normally publishes a notice of proposed rulemaking in the Federal Register and invites public comment on the proposed rule before the provisions of the rule take effect. The APA authorizes the agency to waive these procedures, however, if it finds good cause that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Further, the APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the *Federal Register*. This 30-day delay in effective date can be waived, however, if the agency finds good cause to support an earlier effective date.

Finally, the Congressional Review Act (CRA) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public comment procedures are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines.

CMS finds good cause to waive notice and comment rulemaking and the effective date delays under the APA and the CRA for this IFC. It argues that in light of the COVID-19 pandemic, it is critically important that the policies in this IFC be implemented as quickly as possible and a delay would contribute to additional negative health outcomes for patients including loss of life and be contrary to the public interest. Justifications offered in discussing the waivers include the following:

- The existing failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements;
- The ongoing risk of new COVID-19 variants;
- The potential harmful impact of unvaccinated healthcare workers on patients;
- Continuing strain on the health care system, particularly from Delta-variant-driven surging case counts beginning in summer 2021;
- The demonstrated efficacy, safety and real-world effectiveness of available vaccines;
- Observed efficacy of COVID-19 vaccine mandates in other settings; and
- Calls from numerous stakeholders for Federal intervention.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, CMS is required to provide a 30-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that it solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of an agency's estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

CMS estimates two types of burden for each of the provider and supplier types impacted by the IFC (with one exception described below): (1) The cost of reviewing and updating policies and procedures to ensure they comply with the requirements in the rule; and (2) the burden of meeting the documentation requirements established by the rule. The documentation burden incorporates the provider's duty to determine that its staff are vaccinated, the related documentation requirements, as well as the more lengthy requirements related to reviewing exemption requests, and documenting those requests and their final determinations.

CMS does not provide an estimate of the documentation burden for LTC facilities because that burden has already been accounted for in OMB Control No. 1938-1363. CMS notes that it expects that many providers and suppliers may already have some policies, procedures and documentation practices in place. It doesn't have the data to account for those existing policies and practices, so the estimates presented below assess the burden for all facilities without regard to whether or not their policies are already consistent with the IFC.

In total, CMS estimates the burden of the IFC's requirements to cost $136 million. Table 3 of the published rule provides estimates of the annual hourly wages used in the estimates of burden for each provider and supplier type. The numbers of providers and suppliers impacted were drawn from the Quality, Certification & Oversight Reports (QCOR) website at https://qcor.cms.gov/main.jsp.

The burden estimate for each type of provider or supplier is summarized in Table 3 in the IFC. The table below incorporates figures from Table 3 as well as data presented in the preamble to summarize the burden for each provider and supplier type impacted.

Summary of Information Collection Burden

Provider or Suppler	Number Impacted	Average Cost per Provider or Supplier	Total Cost ($ in millions)
Ambulatory Surgical Centers	6,071	$ 1,023	$ 6.2
Hospices	5,556	$ 1,279	$ 7.1
PRTF's	357	$ 1,354	$ 0.5
PACE programs	141	$ 1,273	$ 0.2
Hospitals[1]	5,294	$ 5,534	$ 45.7
LTC Facilities[2]	15,401	$ 405	$ 6.2
ICFs-IIDs	5,780	$ 823	$ 4.7
HHAs	11,649	$ 1,879	$ 21.9
CORFs	159	$1,279	$ 0.2

CAHs[3]	1,358	$1,120	$ 1.5
Organizations[4]	2,078	$ 901	$ 1.9
CMHCs	129	$ 11,355	$ 1.5
HIT suppliers[5]	317	$ 1,138	$ 0.2
RHCs and FQHCs	15,317	$ 2,024	$ 31.0
ESRD facilities	7,893	$ 908	$ 7.1

[1] Incorporates the documentation burden for CAHs here because CMS did not have separate estimates of the number of staff in CAHs versus other hospitals.
[2] Includes only the estimate for updating policies and procedures. The documentation burden has already been accounted for in OMB Control No. 1938-1363.
[3] Includes only the estimate for updating policies and procedures. Documentation costs are incorporated in hospitals estimate.
[4] Includes clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services.
[5] The total burden for HIT suppliers ($0.2 million) presented in this table is drawn from Table 4. HPA calculates the total burden based on the figures presented in the preamble to be $0.4 million, however.

V. Regulatory Impact Analysis

CMS has examined the effects of the IFC pursuant to Executive Order 13563, Executive Order 12866, the Regulatory Flexibility Act and other authorities. They have determined that the IFC is "economically significant" within the meaning of Executive Order 12866 because it is expected have economic impacts of $100 million or more in any one year. Accordingly, CMS provides an analysis of the potential costs associated with these rules which are summarized. It notes that certain benefits, in particular the value of lives extended and a reduction in the costs of medical care for those not treated for COVID-19, were not able to be quantified.

Estimated costs that were quantified are provided in Table 7 of the IFC, duplicated below.

Table 7: Estimate of Total First Year Costs ($, millions)

Cost Category	Estimate
Information Collection Costs	136
Counseling and Incentive Costs	180
Vaccination Costs	466
Disruptions to Staffing and Services	600
TOTAL	1,382

In addition to the information collection costs which are described above, CMS estimates costs for counseling and incentives, vaccinations, and staff and services disruptions:

- The IFC does not require vaccine counseling or education services, but CMS anticipates that some providers and suppliers will conduct those activities as part of their procedures for ensuring compliance with the regulations. It estimates one hour at an hourly cost for an RN ($75) for 2.4 million individuals.

- The costs of the vaccination itself will be born by the federal government. Those costs are comprised of $120 for the vaccine and $75 for administering the vaccine to 2.4 million employees for a total of $466 million.
- Disruptions to staffing and services could occur if individuals leave employment at Medicare- or Medicaid-certified facilities and those facilities need to replace those individuals. The $600 million figure is described as an example of such costs and is based on the hiring costs for workers in long-term care facilities of between $4,000 and $6,000 per person; additional hires of about 5 percent of the workforce or about 2.4 million workers.

CMS also provides two tables: Table 6 and Table 7 that include estimates of the number of staff, vaccinated staff, and unvaccinated staff by provider type.

Federalism

Executive Order 13132 establishes requirements that an agency must meet when it promulgates a rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

CMS explains that the IFC would pre-empt State laws that prohibit employers from requiring their employees to be vaccinated for COVID-19. Such laws that forbid employers from imposing vaccine requirements on employees are seen as directly conflicting with CMS' statutory health and safety authority to require vaccinations for staff of the providers and suppliers subject to this rule.

Further the IFC preempts the applicability of any State or local law that permits broader grounds for exemptions from vaccine requirements than under this IFC. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule. The agency states that this rule is the minimum regulatory action necessary to achieve the objectives of the statute given the contagion rates of the existing strains of coronavirus and their disproportionate impacts on Medicare and Medicaid beneficiaries.