



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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[CMS-3415-F, CMS-3414-F, CMS-3401-F]

RIN 0938-AU75, 0938-AU57, 0938-AU33

Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) to Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements

AGENCY: Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule removes expired language addressing staff and patient COVID-19 testing requirements for LTC Facilities issued in the interim final rule with comment “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” published in the September 2, 2020 **Federal Register**. The rule also finalizes requirements for these facilities to provide education about COVID-19 vaccines and to offer COVID-19 vaccines to residents, clients, and staff. In addition, the rule withdraws the regulations in the interim final rule with comment (IFC) “Omnibus COVID-19 Health Care Staff Vaccination” published in the November 5, 2021 **Federal Register**, and finalizes certain provisions of the “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’ IFC, published in the May 13, 2021 **Federal Register**.

DATES: The regulations in this final rule are effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the “coronavirus disease 2019” (COVID-19) outbreak caused by “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2) a “Public Health Emergency of International Concern.” On January 31, 2020, pursuant to section 319 of the Public Health Service Act (PHSA) (42 U.S.C. 247d), the Secretary of the Department of Health and Human Services (Secretary) determined that a public health emergency (PHE) exists for the United States. On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. The President of the United States declared the COVID-19 pandemic a national emergency on March 13, 2020. Pursuant to section 319 of the PHSA, the determination that a PHE continues to exist may be renewed at the end of each 90-day period.¹ The initial determination that a PHE for COVID-19 exists and had existed since January 27, 2020, lasted for 90 days, and was renewed by the Secretary on April 21, 2020; July 23, 2020; October 2, 2020; January 7, 2021; April 15, 2021; July 19, 2021; October 15, 2021; January 14, 2022; April 12, 2022; July 15,

¹ <https://aspr.hhs.gov/legal/PHE/Pages/Public-Health-Emergency-Declaration.aspx>.

2022; October 13, 2022; January 11, 2023; and February 9, 2023.² The COVID-19 PHE expired on May 11, 2023.

COVID-19 has had significant negative health effects on individuals, communities, and the nation as a whole. Over a year ago, in September 2021, COVID-19 overtook the 1918 influenza pandemic as the deadliest disease in American history.³ According to the Centers for Disease Control and Prevention (CDC), just over 6 million patients admitted to hospitals in the United States have been confirmed positive with COVID-19 infection since August 1, 2020, and approximately 1.1 million COVID-19 deaths have been reported in the United States as of April 14, 2023. In light of our responsibility to protect the health and safety of individuals receiving care and services from Medicare- and Medicaid-certified providers and suppliers, and CMS' statutory authority, as outlined in section I.E. of this final rule, to establish health and safety regulations, we have been compelled to act throughout the COVID-19 pandemic. While a comprehensive discussion of CMS' regulatory responses during the PHE is outside the scope and purpose of this final rule, we note that CMS issued several interim final rules with comment periods (IFCs) during the COVID-19 PHE to help minimize the spread and impact of SARS-CoV-2. Some of these IFCs established new health and safety standards, known as the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), or Requirements for Participation, for providers and suppliers who participate in the Medicare and Medicaid programs. Several of the policies in these IFCs have been further addressed in final rules and through the COVID-19 vaccination quality measures which have been proposed for adoption in multiple CMS quality reporting and payment programs (for example, the "Measures Under Consideration" (MUC) List issued by CMS on December 1, 2022). These IFCs, final rules, and quality reporting and payment programs reflect the scaled progression of CMS' response during the COVID-19 PHE as both the science and epidemiology pertaining to COVID-19 evolved.

² <https://aspr.hhs.gov/legal/PHE/Pages/default.aspx>.

³ <https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/>.

On September 2, 2020, we issued an IFC titled “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (85 FR 54820), otherwise known as the “LTC facility testing IFC.” This IFC revised regulations to strengthen CMS’ ability to enforce compliance with Medicare and Medicaid long-term care facility requirements for reporting information related to COVID-19, established a new requirement for hospitals and critical access hospitals (CAHs) to track the incidence and impact of COVID-19, and established a new requirement for LTC facilities to test residents and staff for COVID-19 applicable for the duration of the PHE. We subsequently finalized provisions addressing the hospital and CAH COVID-19 reporting requirements in the final rule “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation” on August 10, 2022 (87 FR 48780) (“FY 2023 Hospital Inpatient Prospective Payment System final rule”).

On May 13, 2021, we issued an IFC titled “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), otherwise known as the “educate and offer IFC.” This IFC revised the requirements for LTC facilities and CoPs for ICFs-IID to require the provision of COVID-19 vaccination education and to offer vaccines to residents, clients, and staff. The IFC also revised the infection control requirements for LTC facilities to include COVID-19 data reporting. We subsequently finalized data reporting requirements for LTC facilities with revisions in the final rule “Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update;

Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities,” published in the November 9, 2021 **Federal Register** (86 FR 62240, 62421) (“calendar year (CY) 2022 Home Health final rule”). These revisions established a sunset date for most COVID-19 reporting requirements for LTC facilities. Specifically, LTC facilities must report all required data until December 31, 2024, as determined by the Secretary.

On November 5, 2021, we issued the interim final rule “Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination” (86 FR 61555), otherwise known as the “staff vaccination IFC.” This IFC revised the requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs to include requirements regarding development and implementation of policies and procedures to ensure COVID-19 vaccination of staff.

Throughout the COVID-19 PHE, we implemented and revised regulations to reflect lessons learned and emerging data and knowledge to protect the health and safety of individuals that receive care and services from Medicare- and Medicaid-certified providers and suppliers. For example, the educate and offer IFC-required LTC facilities and ICFs-IID that furnish care and services to populations identified at increased risk for severe health outcomes due to COVID-19 infection, to provide COVID-19 vaccination education and to offer vaccines to residents, clients, and staff. These requirements are generally referred to as the “educate and offer” provisions. Nonetheless, evidence continued to demonstrate that unvaccinated health care staff presented risks to patient safety across health care settings, and that too few health care staff were getting vaccinated. At the same time, the advent of a more contagious and severe variant (Delta)--and the recognition that additional variants were likely to emerge and, together with seasonal respiratory illnesses, increased the pressure on the health care system--indicated a need

for CMS to take additional action.

Accordingly, we issued the staff vaccination IFC, which required most Medicare- and Medicaid-certified providers and suppliers to ensure health care staff completed their COVID-19 primary vaccine series. As discussed in the educate and offer IFC and the staff vaccination IFCs, COVID-19 vaccination is one of the most important tools in the multi-pronged approach for reducing health system burden, safeguarding health care workers and the people they serve, and mitigating the overall impact of the COVID-19 pandemic. Food and Drug Administration (FDA)-approved and FDA-authorized COVID-19 vaccines in use in the United States are both safe and highly effective at protecting vaccinated people against severe COVID-19.^{4,5}

As conditions and circumstances of the COVID-19 PHE have evolved, so too has CMS' response. At this point in time, we believe that the risks targeted by the staff vaccination IFC have been largely addressed, so we are now aligning our approach with those for other infectious diseases, specifically influenza. Accordingly, CMS intends to encourage ongoing COVID-19 vaccination through its quality reporting and value-based incentive programs in the near future. The statute requires that the Secretary establish a pre-rulemaking process for the selection of certain quality measures for use by HHS.⁶ The pre-rulemaking process requires that HHS make publicly available, not later than December 1 annually, a list of quality and efficiency measures HHS is considering to adopt, through the rulemaking process, for use in certain Medicare quality programs and for use in publicly reported performance information in any Medicare program. This list is known as the Measures Under Consideration (MUC) List. Table 1 shows the COVID-19 vaccination measures under consideration, as published on December 1, 2022, for patients and health care personnel, including measure title, measure description, and applicable quality programs. We note that on April 18, 2023, FDA revised the Emergency Use

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>.

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/index.html>.

⁶ See section 1890A(a) of the Act (42 U.S.C. 1395aaa-1(a)) and section 1890(b)(7)(B) of the Act (42 U.S.C. 1395aaa(b)(7)(B)).

Authorizations (EUAs) for the Pfizer and Moderna mRNA vaccines to make several changes to the authorized dosing regimen and schedule.⁷ Among other changes, the revised EUAs for the mRNA vaccines no longer refer to “primary series” and “booster” doses. In addition, previously unvaccinated individuals 6 years through 64 years of age (other than those with certain immunocompromising conditions) are only authorized to receive a single dose of a COVID-19 vaccine. They will not receive an mRNA “series.” These measures may be revised from their initial design but we include the MUCs here as an illustration of CMS’s interest in pursuing implementation of measures that encourage uptake of COVID-19 vaccines. The use of such quality measures may ultimately affect ratings on the various “Compare” (such as “Hospital Compare”) websites and may affect payment in various “value-based purchasing” programs, but would not affect the ability of the provider or supplier to participate in the Medicare program. Information about the MUC List is available on the CMS Measures Management System (MMS) website at <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

⁷ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines>.

TABLE 1: COVID-19 Vaccination MUC for Use in Certain Medicare Quality Programs as Published December 1, 2022

Measure	Description	Quality Programs
Adult COVID-19 Vaccination Status	Percentage of patients aged 18 years and older seen for a visit during the performance period who have ever completed or reported having ever completed a COVID-19 vaccination series and one booster dose	Merit-based Incentive Payment System (MIPS)
COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) (2022 revision)	Percentage of healthcare personnel who are considered up-to-date on their COVID-19 vaccinations per the CDC's latest guidance	Ambulatory Surgical Center Quality Reporting Program (ASCQR) Hospital Inpatient Quality Reporting Program (Hospital IQR Program) Hospital Outpatient Quality Reporting Program (Hospital OQR Program) Hospital Value-Based Purchasing Program (HVBP) Hospital-Acquired Condition Reduction Program (HACRP) Inpatient Psychiatric Facility Quality Reporting Program (IPFQR) Inpatient Rehabilitation Facility Quality Reporting Program (IRFQRP) Long-Term Care Hospital Quality Reporting Program (LTCHQRP) Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (PCHQRP) Skilled Nursing Facility Quality Reporting Program (SNFQRP) End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date	Percentage of patients who are considered up-to-date on their COVID-19 vaccinations per the CDC's latest guidance	Home Health Quality Reporting Program (Home Health QRP) SNFQRP IRFQRP LTCHQRP

Quality measures would provide a means to monitor COVID-19 vaccination rates among patients and health care personnel in multiple entities across the health system, including inpatient, outpatient, congregate care, and home-based care settings. Moreover, public reporting of quality measures increases the involvement of leadership in quality improvement, creates a sense of accountability, helps to focus organizational priorities, supports transparency, and provides a means of delivering important information to consumers.⁸

As discussed further in section I.E. of this final rule, section 902 of the Medicare

⁸ <https://qualitynet.cms.gov/inpatient/public-reporting/public-reporting>.

Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that the publication of Medicare final regulations shall not exceed 3 years after publication of the preceding proposed or interim final regulation, except under exceptional circumstances. Thus, consistent with section 902 of the MMA, the requirements of the IFCs discussed in this rule would have expired if not finalized within 3 years of publication.

As the COVID-19 pandemic has continued to evolve and circumstances have normalized, we have continued to evaluate the evolving clinical and epidemiological circumstances of the COVID-19 pandemic and the requirements issued in the IFCs, particularly those requirements that have not been finalized to date, for the purpose of determining the appropriate disposition of those requirements. The central consideration in our evaluation and determination is helping to protect the health and safety of individuals that receive care and services from Medicare- and Medicaid-certified providers and suppliers.

This final rule addresses the disposition of regulations issued through three IFCs, specifically: the health care staff vaccination requirements issued in the staff vaccination IFC; the education and vaccine offering requirements issued in the educate and offer IFC; and the LTC testing IFC. Due to the broad scope and scale of the Omnibus COVID-19 Health Care Staff Vaccination IFC (staff vaccination IFC), we discuss it as the primary focus for policies addressed in this rule. Thus, throughout this document, we address the staff vaccination IFC first followed by the educate and offer IFC and the LTC testing IFC.

B. Omnibus COVID-19 Health Care Staff Vaccination

On November 5, 2021, we published the staff vaccination IFC, which revised the health and safety requirements that most providers and suppliers must meet to participate in the Medicare and Medicaid programs. The revisions established requirements regarding COVID-19 staff vaccination for the Medicare- and Medicaid-certified providers and suppliers included in the IFC. The following providers and suppliers were regulated by the staff vaccination IFC, listed in the numerical order of the relevant Code of Federal Regulations (CFR) sections:

- Ambulatory Surgical Centers (ASCs) – § 416.51(c).
- Hospices – § 418.60(d).
- Psychiatric Residential Treatment Facilities (PRTFs) – § 441.151(c).
- Programs of All-Inclusive Care for the Elderly (PACE) Organizations – § 460.74(d).
- Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children’s hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities) – § 482.42(g).
- LTC Facilities, including skilled nursing facilities (SNFs) and nursing facilities (NFs), generally referred to as nursing homes – § 483.80(i).
- ICFs-IID – § 483.430(f).
- Home Health Agencies (HHAs) – § 484.70(d).
- Comprehensive Outpatient Rehabilitation Facilities (CORFs) – § 485.70(n).
- Critical Access Hospitals (CAHs) – § 485.640(f).
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-language Pathology Services (Organizations) – § 485.725(f).
- Community Mental Health Centers (CMHCs) – § 485.904(c).
- Home Infusion Therapy (HIT) Suppliers – § 486.525(c).
- Rural Health Clinics (RHCs) and Medicare Federally Qualified Health Centers (FQHCs) – § 491.8(d).
- End-Stage Renal Disease (ESRD) Facilities – § 494.30(b).

We discuss the specific requirements of the staff vaccination IFC in section II.A. of this rule. In section III.A. of this final rule, we address the public comments submitted to CMS regarding the staff vaccination IFC. We then discuss the withdrawal of regulations pertaining to the staff vaccination IFC in section IV.A. of this rule.

While the requirements established by the staff vaccination IFC were necessary to protect

the health and safety of residents, clients, patients, and PACE Organization participants at the time of publication, circumstances of the COVID-19 pandemic have evolved, as has CMS' response, as discussed throughout this rule. As mentioned above, based on an evaluation of the evolving clinical and epidemiological circumstances of the COVID-19 pandemic, increased vaccine uptake, declining infection and death rates, decreasing severity of disease, increased instances of infection-induced immunity, public comments submitted to CMS, and the addition of COVID-19 vaccination quality measures to quality improvement and reporting programs, we believe regulations regarding COVID-19 vaccination of health care staff are no longer necessary. Therefore, in this rule, we are withdrawing language on COVID-19 health care staff vaccination requirements issued in the staff vaccination IFC. COVID-19 vaccination policies and procedures for health care staff will no longer be required under the CoPs, CfCs, and requirements.

C. COVID-19 Vaccine “Educate and Offer” Requirements for LTC Facilities and ICFs-IID

On May 13, 2021, CMS issued the educate and offer IFC, which revised the health and safety requirements that LTC facilities and ICFs-IID must meet to participate in the Medicare and Medicaid programs. The IFC established requirements that these facilities provide COVID-19 vaccination education to residents, clients, and staff, and to offer COVID-19 vaccines to these populations, referred to as the “educate and offer” provisions. The IFC also established additional infection control requirements for LTC facilities, as well as requirements to report certain COVID-19 data: these requirements have already been finalized through previous rulemaking (86 FR 62240).⁹ We discuss these educate and offer provisions of the IFC in section II.B. of this rule. In section III.B. of this final rule, we address the public comments submitted to CMS regarding the educate and offer provisions. We then discuss the final regulatory changes pertaining to the educate and offer provisions in section IV.B. of this final rule.

Individuals living in congregate care settings, such as LTC facilities and ICFs-IID, are at

⁹ <https://www.federalregister.gov/documents/2021/11/09/2021-23993/medicare-and-medicaid-programs-cy-2022-home-health-prospective-payment-system-rate-update-home>.

greater risk than the general population for contracting SARS-CoV-2 and developing severe health outcomes due to COVID-19,^{10,11} and they rely on facility staff to provide for their daily needs, including access to health care services such as vaccination. As discussed in section III.B. of this rule, public commenters acknowledge these risks. Consistent with our approach to staff vaccinations for COVID-19, we are moving to align our approach with existing regulations addressing other infectious diseases, such as influenza and pneumococcal disease. Therefore, we are finalizing the educate and offer requirements on a permanent basis. This complements the proposed adoption of the “COVID-19 Vaccine: Percent of Patients/ Residents Who are Up to Date (Patient/ Resident COVID-19 Vaccine) measure” and the “COVID-19 Vaccination Coverage among Healthcare Personnel (HCP COVID-19 Vaccine) measure” as issued in the “Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF); Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2024” proposed rule (88 FR 21316) (“2024 SNF Prospective Payment System proposed rule”). Given that the educate and offer provisions are existing requirements for LTC facilities and ICFs-IID, the requirements will remain effective after the publication date of this final rule.

D. COVID-19 Testing Requirement for LTC Facilities

On September 2, 2020, CMS published the LTC facility testing IFC, which revised the infection control requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. This IFC established requirements applicable for the duration of the PHE for LTC facilities to test their staff and residents for COVID-19 based on parameters set forth by the Secretary in a manner consistent with current professional standards of practice. This IFC also established COVID-19 reporting requirements for hospitals and CAHs which have been finalized

¹⁰ https://www.cdc.gov/coronavirus/2019-ncov/your-health/understanding-risk.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Findex.html.

¹¹ <https://www.cdc.gov/coronavirus/2019-ncov/community/community-congregate-living-settings.html>.

through previous rulemaking (87 FR 48780). As previously discussed, LTC facility residents are more susceptible to contracting COVID-19 and developing severe symptoms. This highlights the importance of practicing preventative measures in order to mitigate the risk of transmission and control the spread of COVID-19 among residents and staff of LTC facilities. At the time of publication, these provisions were necessary to protect the health and safety of both residents and health care personnel of LTC facilities, as there were limited treatments for COVID-19 and vaccines were not yet available. As the COVID-19 PHE has concluded, we are deleting expired text related to the LTC facility testing requirements effective the publication date of this final rule.

CMS continues to emphasize the importance of practicing preventative measures in order to reduce the transmission of COVID-19. Moving forward, CMS aims to use quality reporting and value-based incentive programs to encourage health care facilities to practice preventative measures against COVID-19. We discuss the LTC facility testing requirements of the IFC in section II.C. of this rule. In section III.C. of this final rule, we address the public comments submitted to CMS regarding the LTC facility testing requirements. We then discuss the final regulatory changes pertaining to the educate and offer provisions in section IV.C. of this final rule.

E. Statutory Authority

Various sections of the Social Security Act (the Act) define the types of providers and suppliers that may participate in Medicare and Medicaid programs and list the requirements that each provider and supplier must meet to be eligible for participation. Statutory provisions applicable to each provider or supplier type either authorize the Secretary to establish other requirements as necessary to protect the health and safety of patients or, in some cases, to establish such additional criteria as the Secretary may require. Although the wording of such authority differs slightly between provider and supplier types, we have interpreted all of these provisions as at minimum permitting the Secretary to establish mandatory requirements to

enhance the health and safety of patients. In addition, parallel Medicaid statutes provide authority to establish requirements to protect the health and safety of patients. Such requirements include the CoPs for providers, CfCs for suppliers, and requirements for LTC facilities. The CoPs, CfCs, and requirements are intended to protect public health and safety and promote high-quality care for all persons. Furthermore, the PHSA sets forth additional regulatory requirements that certain Medicare providers and suppliers are required to meet in order to participate. Table 2 lists the statutory authority by provider and supplier type for which we are issuing the requirements in this final rule:

TABLE 2: Statutory Authority by Provider and Supplier Type

Provider and Supplier Type	Statutory Authority
Ambulatory Surgical Centers (ASCs)	Sections 1832(a)(2)(F)(i), and 1833 (i)(1)(A) of the Act
Hospices	Section 1861(dd) of the Act
Psychiatric Residential Treatment Facilities (PRTFs)	Section 1905(h)(1) of the Act
Programs of All-Inclusive Care for the Elderly (PACE) Organizations	Sections 1894(f), and 1934(f) of the Act
Hospitals	Section 1861(e)(9) of the Act
Long Term Care (LTC) Facilities	Sections 1819(d)(4)(B), 1819(f)(1), and 1919(d)(4)(B) and (f)(1) of the Act
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	Section 1905(d)(1) of the Act
Home Health Agencies (HHAs)	Sections 1861(m), 1861(o), and 1891 of the Act
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	Section 1861(cc)(2)(J) of the Act
Critical Access Hospitals (CAHs)	Section 1820(e) of the Act
Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (Organizations)	Section 1861(p)(4)(A)(v) of the Act
Community Mental Health Centers (CMHCs)	Sections 1861(ff)(3)(b)(iv), 1832(a)(2)(J), and 1866(e)(2) of the Act
Home Infusion Therapy (HIT) Suppliers	Section 1861(iii)(3)(D)(i)(IV) of the Act
Rural Health Clinics (RHCs)/ Federally Qualified Health Centers (FQHCs)	Sections 1861(aa) and 1905(l)(2)(B) of the Act
End-Stage Renal Disease (ESRD) Facilities	Section 1881(b)(1)(A) of the Act

We note that the appropriate term for an individual receiving care and services differs depending upon the provider or supplier type. For example, for hospitals and CAHs, the appropriate term is “patient,” but for ICFs-IID, it is “client.” Further, LTC facilities have “residents” and PACE Organizations have “participants.” In this final rule, the appropriate terms are used when discussing one or two provider or supplier types; however, when we are discussing three or more provider and supplier types, we use the general term “patient.”

Similarly, despite the different terms used for specific provider and supplier entities (such as campus, center, clinic, facility, organization, or program), when we are discussing three or more provider and supplier types, we use the general term “facility.”

F. Requirements for Issuance of Regulations

Section 902 of the MMA amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule withdraws the regulatory provisions set forth on November 5, 2021, in the Omnibus COVID-19 Health Care Staff Vaccination IFC and deletes expired provisions set forth on May 13, 2021, in the LTC facility testing IFC. Also, this final rule finalizes the “educate and offer” provisions set forth on May 13, 2021, in the COVID-19 Vaccine Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff IFC. This final rule has been published within the 3-year time limit imposed by section 902 of the MMA.

G. Enforcement of Staff Vaccination Provisions

Federal rules generally become effective 60 days after publication; however, the COVID-19 PHE expired on May 11, 2023. Our decision to terminate the omnibus facility staff vaccination requirements in this final rule reflect our determination that the emergency circumstances which occasioned these vaccination provisions no longer exist. Since facilities are no longer operating under PHE circumstances, and considering the lower policy priority of enforcement within the remaining time, we will not be enforcing the staff vaccination provisions between now and [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

II. Provisions of the Interim Final Regulations

In this section, we review the requirements issued in the staff vaccination IFC, the educate and offer IFC, and the LTC facility testing IFC. In section II.A. of this rule, we summarize and discuss the requirements of the staff vaccination IFC. We then summarize and discuss the educate and offer provisions in the educate and offer IFC in section II.B. of this final rule. Lastly, we summarize and discuss the LTC testing IFC in section II.C. of this final rule.

A. Omnibus COVID-19 Health Care Staff Vaccination

As discussed in section I. of this rule, we established COVID-19 staff vaccination requirements for most Medicare- and Medicaid-certified providers and suppliers in an IFC published in November 2021. Those provisions reflected a common set of requirements with no substantive regulatory differences across facility types, added to the CoPs, CfCs, and requirements, as applicable, under the relevant CFR section as listed in section I.B. of this final rule. Next, we briefly discuss these common provisions. We then discuss any additional revisions for specific provider and supplier types issued by CMS in the staff vaccination IFC due to unique circumstances.

1. Common Requirements in the Staff Vaccination IFC

The IFC requires each applicable facility to develop and implement policies and procedures under which staff complete a primary COVID-19 vaccine series. Those vaccination policies and procedures must apply to current and new staff, to include volunteers and individuals under contract or arrangement, that provide any care, treatment, or other services for the facility or its patients, regardless of clinical responsibility or degree of anticipated patient contact. Vaccination is required for all staff that interact with other staff or patients in any location, such as clinics, homes, or other sites of care and services.

As discussed in the IFC, some staff are not subject to the vaccination requirements, including but not limited to those who provide services 100 percent remotely and “one-off” vendors, volunteers, and professionals who infrequently provide ad hoc non-health care services,

such as annual elevator inspection, delivery, and repair personnel. When determining whether to require COVID-19 vaccination of an individual who does not clearly fall within the classification of staff, we encouraged facilities to consider frequency of presence, services provided, and proximity to patients and staff. We also strongly encouraged facilities to facilitate the vaccination of all individuals who provide services infrequently and are not otherwise subject to the requirements in the IFC to the extent opportunity exists and resources allow.

In the IFC, we required facilities to ensure that staff are “fully vaccinated” for COVID-19, defined as 2 weeks or more since completion of a primary vaccination series. We also required facilities to have a process for tracking and securely documenting the COVID-19 vaccination status of staff who obtain any booster doses as recommended by the CDC. For those staff who are not “fully vaccinated” for COVID-19, we required facilities to establish and implement a process that provides additional precautions to minimize the spread of COVID-19.

The IFC required facilities to track and securely document the vaccination status of each staff member. All medical records, including vaccine documentation, were to be kept confidential and stored separately from an employer’s personnel files, pursuant to the Americans with Disabilities Act (ADA) and the Rehabilitation Act.

We described these documentation requirements in the IFC as an ongoing process due to the onboarding of new staff, and we provided examples of: (1) appropriate places for vaccine documentation, such as an immunization record, health information files, or other relevant documents; and (2) acceptable forms of proof of vaccination, such as a CDC COVID-19 vaccination record card (or a legible photo of the card) or documentation of vaccination from a health care provider, electronic health record, State immunization information system record, or a reasonable equivalent for those individuals vaccinated outside of the United States.

Further, through the IFC, we required facilities to establish and implement a process by which staff may request an exemption from the COVID-19 vaccination requirement based on: (1) an applicable Federal law, such as the ADA, section 504 of the Rehabilitation Act, section

1557 of the Affordable Care Act (ACA), and Title VII of the Civil Rights Act that prohibit discrimination based on race, color, national origin, religion, disability, and sex, including pregnancy; and (2) recognized clinical contraindications to receipt of a COVID-19 vaccine. Facilities had to have a process for collecting and evaluating exemption requests, including tracking and securely documenting the required information.

We acknowledged in the IFC that certain allergies or medical conditions may be clinical contraindications to receiving a COVID-19 vaccine, and we referred facilities to the CDC page “Use of COVID-19 Vaccines in the United States: Interim Clinical Considerations” which can be accessed at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>. The IFC required facilities to make contingency plans in consideration of staff who are not “fully vaccinated” to ensure that those staff will soon be vaccinated and will not provide care, treatment, or other services for the facility or its patients until such time as those staff complete a primary vaccination series for COVID-19 and are considered “fully vaccinated.” This planning must also address the safe provision of care and services by staff who request an exemption from vaccination that is under consideration and by staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical reasons.

We discussed in the IFC that contingency planning may extend beyond the specific requirements of the rule, to address topics such as staffing agencies that can supply vaccinated staff if some of a facility’s staff are unable to work. We also discussed special precautions to be taken in the event of, for example, a regional or local emergency declaration, such as for a hurricane or flooding, which necessitated the temporary utilization of unvaccinated staff, in order to assure the health and safety of patients. We also acknowledged in the IFC that facilities may already have contingency plans that meet the requirements in their existing emergency preparedness policies and procedures.

2. Additional Requirements in the Staff Vaccination IFC for Specific Provider and Supplier Types

In addition to the common set of provisions issued in the staff vaccination IFC for all applicable facility types, we varied specific provisions of the regulations, where applicable, for specific provider and supplier types. These various provisions for specific provider and supplier types were necessary due to the unique content of regulations in place at the time the staff vaccination IFC was published, for Psychiatric Residential Treatment Facilities (PRTFs), HIT suppliers, RHCs/FQHCs; LTC facilities and ICFs-IID; and CORFs.

As discussed in the staff vaccination IFC, PRTFs, HIT Suppliers, and RHCs/FQHCs did not have specific infection control and prevention regulations at the time the IFC was published. Therefore, for PRTFs at § 441.151(c)(3)(iii), HIT suppliers at § 486.525(c)(3)(iii), and RHCs/FQHCs at § 491.8(d)(3)(iii), we required a process for ensuring adherence to nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19. This process included the implementation of additional precautions for all staff who were not fully vaccinated for COVID-19.

At the time the staff vaccination IFC was published, LTC facilities had existing regulations at § 483.80(d)(3)(v) that required facilities to educate all residents and staff about the COVID-19 vaccines and to offer the vaccines, when available. Likewise, at the time the IFC was published, ICFs-IID had existing regulations at § 483.460(a)(4)(v) that required facilities to educate all clients and staff about the COVID-19 vaccines and to offer the vaccine, when available. As discussed in section I. of this final rule, those requirements were established by the educate and offer IFC. In the staff vaccination IFC, we revised these requirements by removing language that could have been interpreted as a path by which staff members in LTC facilities and ICFs-IID could bypass the facility's vaccination policies and procedures. This change was necessary because retaining that language originally established by the educate and offer IFC would have been inconsistent with the goals of the staff vaccination IFC. In this final rule, we are finalizing the education and offering provisions of the educate and offer IFC, as amended by

the staff vaccination IFC, and we refer readers to sections I., II.B., III.B., IV.B., V.B, and VI.B. of this final rule for additional information.

Regulations in place at the time that the staff vaccination IFC was published for CORFs at 42 CFR 485.70(a) through (m) identified the qualifications required for personnel, including facility physician, licensed practical nurse, occupational therapist, occupational therapist assistant, orthotist, physical therapist, physical therapist assistant, prosthetist, psychologist, registered nurse, rehabilitation counselor, respiratory therapist, respiratory therapy technician, social worker, and speech-language pathologist. In addition, regulations at § 485.58(d)(4) stated that personnel who do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. In the staff vaccination IFC, we added § 485.70(n) which requires CORFs to develop and implement policies and procedures to ensure COVID-19 vaccination of all facility staff. As discussed in the IFC, we recognize that assisting personnel are used by CORFs, and we established our requirements at § 485.70(a) through (m) to provide a role for personnel that might not meet our education and experience qualifications. However, we did not believe this exception for employees who did not meet our professional requirements should have prohibited us from issuing staff qualifications referencing infection prevention, which we intended to apply to all personnel. Therefore, in the staff vaccination IFC, we revised § 485.58(d)(4) to state that personnel who did not meet the qualifications specified in § 485.70(a) through (m) may be used by the facility in assisting qualified staff.

As noted previously in this rule, we are withdrawing the provisions of the staff vaccination IFC.

B. COVID-19 Vaccine “Educate and Offer” Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff

As discussed in section I. of this final rule, on May 13, 2021, CMS issued the educate and offer IFC. This IFC revised the requirements for LTC facilities and CoPs for ICFs-IID to provide COVID-19 vaccination education and to offer vaccines to residents, clients, and staff,

otherwise known as the “educate and offer” provisions. This IFC also established requirements for COVID-19 data reporting in LTC facilities.

Subsequently, in the “Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities” final rule (86 FR 62240), we finalized the LTC facility reporting requirements from the educate and offer IFC at § 483.80(g)(1) through (3) with some minor modifications.¹² Given that this final rule addresses only the “educate and offer” provisions of the IFC, this section provides a summary of those specific requirements.

1. LTC Facilities

For LTC facilities, the educate and offer IFC established 42 CFR 483.80(d)(3) COVID-19 immunizations, under which facilities must develop and implement policies and procedures to ensure that all of the requirements set forth in that section are followed. Before offering a COVID-19 vaccine, all residents, resident representatives, and staff members are provided with education regarding the benefits, risks, and potential side effects associated with the vaccine. When a COVID-19 vaccine is available to the facility, each resident and staff member is offered a COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized. In situations where COVID-19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with current information regarding those additional doses, including any changes in the benefits or risks and potential side effects associated with the COVID-19 vaccine, before requesting consent for

¹² <https://www.federalregister.gov/documents/2021/11/09/2021-23993/medicare-and-medicaid-programs-cy-2022-home-health-prospective-payment-system-rate-update-home>.

administration of any additional doses.

The regulation states that the resident or resident representative has the opportunity to accept or refuse a COVID-19 vaccine and change their decision. The original regulatory provisions as issued by the educate and offer IFC also permitted staff members to refuse vaccination. However, as discussed in section II.A. of this final rule, the reference to staff members in the refusal provision at § 483.80(d)(3)(v) was removed by the staff vaccination IFC published November 5, 2021. The resident's medical record is documented to reflect, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; each dose of COVID-19 vaccine administered to the resident; or, if the resident did not receive a COVID-19 vaccine due to medical contraindications or refusal. For staff members, the facility maintains documentation related to COVID-19 vaccination that includes, at a minimum, that staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccines; were offered a COVID-19 vaccine or information on obtaining a COVID-19 vaccine; and the COVID-19 vaccine status of staff and related information as indicated by the CDC's National Healthcare Safety Network (NHSN).

In this final rule, we are finalizing the infection control requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs as issued in the educate and offer IFC and amended by the staff vaccination IFC. By doing so, LTC facilities must continue to educate residents, resident representatives, and staff about COVID-19 vaccines and offer a COVID-19 vaccine to residents, resident representatives, and staff, as well as complete the appropriate documentation for these activities. This aligns with the newly-proposed resident and patient vaccination measures as proposed in the 2024 SNF Prospective Payment System proposed rule.¹³

¹³ <https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2024-skilled-nursing-facility-prospective-payment-system-proposed-rule-cms-1779-p>.

Since the COVID-19 pandemic began, many States have passed laws regarding COVID-19 vaccination.¹⁴ Some States have required various individuals to take the vaccine while other States have prohibited the requirement of COVID-19 vaccination. Since LTC facility staff may be required to take a COVID-19 vaccine in some States, or by some employers, we believe it is inappropriate to include explicit permission to refuse in the regulations. In addition, as we noted in the staff vaccination IFC, retaining this language would be contrary to the goals of that IFC, which included protecting the health and safety of residents, clients, and staff. Hence, we are finalizing the provision as amended by the staff vaccination IFC, which provides, at § 483.80(d)(3)(vii) that the facility maintains documentation related to staff COVID-19 vaccination. The documentation must include, at a minimum, evidence that staff were informed about the risks and benefits of the COVID-19 vaccine. The facility must also document that staff were either offered the COVID-19 vaccine or provided with information on acquiring the COVID-19 vaccine. Lastly, the staff's COVID-19 vaccine statuses and any associated information must be documented and reported to the NHSN as indicated by CDC.

2. ICFs-IID

For ICFs-IID, the educate and offer IFC established § 483.430(f), “COVID-19 Vaccination of facility staff,” and § 483.460(a)(4), the educate and offer provisions. Section 483.430(f) requires that each ICF-IID maintain documentation related to its staff that includes, at a minimum, documentation that the staff were provided education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine and were offered a COVID-19 vaccine or information on obtaining the COVID-19 vaccine. Section 483.460(a)(4) requires each ICF-IID to develop and implement policies and procedures to ensure that when a COVID-19 vaccine is available to the facility; each client and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the client or staff

¹⁴ Pekruhn, D and Abbasi, E. “Vaccine Mandates by State: Who is, Who isn’t, and How?” *Leading Age*. <https://leadingage.org/workforce-vaccine-mandates-state-who-who-isnt-and-how/>. Published on January 19, 2022. Accessed on January 17, 2023.

member has already been immunized. Before offering a COVID-19 vaccine, all staff members, clients, and client representatives must be provided with education regarding the benefits and risks and potential side effects associated with the vaccine. In situations where COVID-19 vaccination requires multiple doses, the client, client's representative, or staff member must be provided with current information regarding each additional dose, including any changes in the benefits or risks and potential side effects associated with a COVID-19 vaccine, before requesting consent for administration of each additional doses. The regulation states that the client or client's representative has the opportunity to accept or refuse a COVID-19 vaccine and change their decision. The original regulatory provisions as issued by the educate and offer IFC also permitted staff members to refuse vaccination. However, as discussed in section II.A. of this final rule, the reference to staff members in the refusal provision at § 483.8460(a)(4)(v) was removed by the staff vaccination IFC published November 5, 2021. The ICF-IID must also ensure that the client's medical record is documented with, at a minimum, that the client or client's representative was provided education regarding the benefits and risks and potential side effects of COVID-19 vaccine and each dose of a COVID-19 vaccine administered to the client. The ICF-IID must also document if the client did not receive a COVID-19 vaccine due to medical contraindications or refusal.

In this final rule, we are finalizing the requirements for COVID-19 vaccination of facility staff and "educate and offer" process that ICFs-IID must meet to participate in the Medicare and Medicaid programs, as first set out in the educate and offer IFC and amended by the staff vaccination IFC. By doing so, ICFs-IID must continue to educate clients, client representatives, and staff about COVID-19 vaccines and offer a COVID-19 vaccine to residents and staff, as well as document these activities.

Since the COVID-19 pandemic began, and as noted above for LTC facilities, many States

have passed laws regarding COVID-19 vaccination.¹⁵ Some States have required various individuals to take the vaccine while other States have prohibited requiring COVID-19 vaccination. Since ICF-IID staff may be required to take a COVID-19 vaccine in some States, or by some employers, we believe it is inappropriate to include explicit permission to refuse in the regulations. As we stated above in section II.B.1. of this final rule, reinstating language that directly allows staff to refuse a COVID-19 vaccine would be contrary to the goals of these IFCs, to protect the health and safety of clients and staff in in ICFs-IID. One's ability to be exempt from a vaccination requirement per another statute (such as the ADA) is outside the scope and authority of this rulemaking. Hence, we are finalizing the refusal provision as amended by the staff vaccination IFC.

C. COVID-19 Testing Requirement for LTC Facilities

In the LTC facility testing IFC, we revised the LTC facility infection control requirements applicable for the duration of the PHE at § 483.80 to establish a new, term-limited requirement that LTC facilities to test their facility residents and staff for COVID-19, including individuals providing services under arrangement and volunteers. We required that resident and staff testing in LTC facilities for COVID-19 be conducted based on parameters set forth by the Secretary, applicable during the COVID-19 PHE. These requirements were established in accordance with CDC guidelines titled, Testing Guidelines for Nursing Homes, which explains the high risk of infection, illness, and death for LTC residents and the importance of testing in order to prevent COVID-19 from entering LTC facilities and preventing transmission.¹⁶ Under this requirement, "staff" are considered any individuals employed by the facility, any individuals that have arrangements to provide services for the facility, and any individuals volunteering at the facility. We explained that we only expected individuals who were physically working on-

¹⁵ Pekruhn, D and Abbasi, E. "Vaccine Mandates by State: Who is, Who isn't, and How?" Leading Age. <https://leadingage.org/workforce-vaccine-mandates-state-who-who-isnt-and-how/>. Published on January 19, 2022. Accessed on January 17, 2023.

¹⁶ https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Flong-term-care.html.

site at the facility to be required to be tested for COVID-19.

At § 483.80(h)(1), we required that resident and staff testing for COVID-19 be conducted based on parameters set forth by the Secretary. These parameters may have included but were not limited to: testing frequency; the identification of any facility resident or staff diagnosed with COVID-19 in the facility; the identification of any facility resident or staff with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19; the criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county; the response time for results; and other factors specified by the Secretary that help identify and prevent the transmission of COVID-19. At § 483.80(h)(2), we required that all residents and staff testing be conducted in a manner consistent with current professional standards of practice for conducting COVID-19 tests. This referred to those professional standards that apply at the time that the care or service is delivered, which we acknowledge have evolved and changed over the course of the COVID-19 pandemic. At § 483.80(h)(3)(i), we required that for each instance of resident or staff COVID-19 testing, which included testing of individuals providing services under arrangement and volunteers, the facility document that testing was completed and the results of each staff test. This documentation would have been located in the staff personnel record or the record or file that the facility maintains for individuals who are providing services under arrangement at the facility. Consistent with the documentation requirements we established for LTC facility staff, we required at § 483.80(h)(3)(ii) that the facility document in the resident's medical record that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test. Due to the high transmission rate of COVID-19, we required at § 483.80(h)(4) that the facility take actions to prevent the transmission of COVID-19 when a resident or staff member, including individuals providing services under arrangement and volunteers, presented with symptoms consistent with COVID-19 or who tested positive for COVID-19. We expected facilities to restrict the access to the facility for any staff member--including individuals

providing services under arrangement and volunteers--who presented with symptoms consistent with COVID-19 or who tested positive for COVID-19 until they were deemed to be safe to return to work. We expected facilities to take measures, including resident cohorting, to mitigate the transmission of the virus within the facility when facility residents presented with symptoms consistent with COVID-19 or who tested positive for COVID-19.

We acknowledge that residents and staff may not have consented to being tested for COVID-19. Therefore, at § 483.80(h)(5) we required that the facility have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refused or were unable to test for the virus. We required at § 483.80(h)(6) that the LTC facility coordinate with state and local health departments and Tribal representatives regarding the availability and obtaining of testing supplies and processing test results when necessary. Facilities may also have coordinated with their local certified laboratories covered under Clinical Laboratory Improvement Amendments (CLIA) on the availability of and obtaining of testing supplies and the processing of test results. Access to adequate testing supplies and arrangements for acquiring testing supplies must have been addressed by the facility's infection prevention and control plan. The testing plan must have included any arrangements that were necessary to conduct, process, and receive test results prior to the administration of the required tests. Since the conclusion of the PHE on May 11, 2023, these requirements are no longer applicable.

III. Analysis of and Responses to Public Comments

In this section, CMS discusses the public comments received for the COVID-19 testing requirement for LTC facilities, the staff vaccination IFC, and the "educate and offer" provisions of the COVID-19 Vaccine Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff IFC (educate and offer IFC), published September 2, 2020, November 5, 2021, and May 21, 2021, respectively. We received public comments in response to all three IFCs, which we summarize and discuss in this section.

In this final rule, we are withdrawing the health care staff COVID-19 vaccination provisions issued in the staff vaccination IFC and deleting the expired COVID-19 testing provisions of the LTC testing IFC. We are also finalizing the COVID-19 “educate and offer” provisions established in the educate and offer IFC. In this section we provide a summary of the public comments received and responses to them, and the policies we are finalizing. In section III.A. of this final rule, we discuss the comments and responses pertaining to the COVID-19 health care staff vaccination requirements. In section III.B. of this final rule, we discuss the comments and responses regarding the requirements for LTC facilities and ICFs-IID to educate residents, clients, and staff about COVID-19 vaccines and to offer COVID-19 vaccines when available. Lastly, in section III.C. of this final rule, we discuss the comments and responses concerning the COVID-19 testing requirements for LTC facilities. Due to the high volume of public comments, we have grouped them by themes and similarities for analysis and response.

A. Omnibus COVID-19 Health Care Staff Vaccination (§§ 416.51(c), 418.60(d), 441.151(c), 460.74(d), 482.421(g), 483.80(d)(3)(v) and (i), 483.430(f), 483.460(v), 484.70(d), 485.58(d)(4), 485.70(n), 485.640(f), 485.725(f), 485.904(c), 486.525(c), 491.8(d), 494.30(b))

In response to this IFC, we received approximately 10,102 timely public comments. Of these, roughly 2/3 were virtually identical letters from individuals from around the country urging CMS to retract the rule. Of the remaining 3,175 unique comments, the majority were from individuals, while over 500 of those unique comments were from industry groups or individual commenters who were commenting as representatives of organizations, companies, and other entities. About 2,000 of these unique comments opposed the regulation, while the remainder of the commenters supported the regulation, some offering suggestions as to how CMS could improve the requirements. A summary of the major themes addressed by commenters and our responses follow.

Comment: A significant minority of commenters agreed with our goal to ensure patient health and safety by establishing a COVID-19 health care staff vaccination requirement.

Commenters stated that COVID-19 vaccination is evidence-based, safe, and the best way to prevent serious illness, hospitalization, death, and spread of infection. They indicated that vaccination of health care staff will provide much-needed workforce stability to the health care industry while decreasing demands associated with providing care to health care workers who contract COVID-19. Some of these commenters stated that patients who had delayed receiving care due to concerns of contracting COVID-19 during the provision of their care would now be able to obtain the care they needed. Some of these commenters recommended expanding the scope of the COVID-19 vaccination regulation to include other settings in which health care is provided, such as physician offices and others. Other commenters recommended that in addition to the primary vaccination series, the regulation should require boosters, which provide ongoing protection against COVID-19.

Response: We appreciate the support from commenters and agree that a requirement for COVID-19 vaccination of health care staff was necessary to ensure timely access to care for patients. We also agree that the COVID-19 PHE placed unprecedented, challenging circumstances on the health care industry, and vaccination of health care staff lessened disruptions to care and operations. We commend health care facilities and their staff for their efforts throughout the COVID-19 pandemic, and we share a common commitment to assuring high-quality and safe care for patients, residents, clients, and participants.

As noted in the IFC, the regulation applied only to those Medicare- and Medicaid-certified providers and suppliers listed. The IFC did not directly apply to other health care entities, such as physician offices, because those settings are not regulated by CMS. Most States have separate licensing requirements for health care staff and health care providers that would be applicable to physician office staff and other staff in small health care entities that were not subject to the vaccination requirements in the IFC. We also noted that health care and other entities providing services under contract for a Medicare- and Medicaid-certified provider and supplier listed in the IFC were indirectly subject to the requirements of the rule. Moreover, we

noted that entities not covered by the IFC may have been subject to other vaccination requirements, such as those issued by State governments for certain types of workplaces.

We thank commenters for recognizing the importance of staying up-to-date with COVID-19 vaccines and boosters. Boosters have been an important part of protecting people from getting seriously ill or dying from COVID-19.¹⁷ Additionally, the newer bivalent vaccines contain an Omicron component to offer better protection against COVID-19 caused by the Omicron variant and its subvariants than the earlier, monovalent vaccines. In April 2023, the EUAs for the bivalent vaccines were revised to simplify the vaccination schedule for most individuals, which included authorizing the current bivalent vaccines for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations.^{18,19} All individuals aged >6 months are recommended to receive at least one dose of bivalent vaccine for COVID-19 under current recommendations.²⁰ Additional information regarding vaccine guidance can be found at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>.

At the time the IFC was issued, the CDC did not include boosters in their definition of “fully vaccinated.” Instead, a person was considered to be fully vaccinated 2 weeks after receiving the last dose of a primary vaccine series.²¹ Since the IFC was issued, CDC shifted to using the terminology “up to date”. Individuals 6 years of age and older are considered “up to date” when they have received one updated Pfizer-BioNTech or Moderna COVID-19 vaccine.²² As of May 2, 2023, the CDC recommends that individuals 6 months of age and older receive a dose of updated (bivalent) vaccine. Certain individuals, depending on age and level of

¹⁷ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

¹⁸ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines>.

¹⁹ <https://www.yalemedicine.org/news/covid-19-variants-of-concern-omicron#:~:text=Omicron%20and%20its%20subvariants,and%20multiply%20in%20other%20countries>.

²⁰ <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html> (accessed May 1, 2023).

²¹ <https://www.cdc.gov/media/releases/2021/p0308-vaccinated-guidelines.html>.

²² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

immunocompromise, may receive additional doses.^{23,24}

We agree with commenters that vaccines continue to be one of the most effective preventative practices against severe COVID-19; however, the effectiveness of the “original” or monovalent vaccines to prevent severe COVID-19 hospitalization and death has remained high, effectiveness to prevent less severe disease has diminished. As previously noted, for reasons discussed throughout this preamble, including declining infection rates and deaths, declining severity, and significant vaccination uptake, we are withdrawing the health care staff COVID-19 vaccination provisions of the IFC. In lieu of regulatory requirements and as previously noted, CMS intends to continue support and encouragement for health care staff vaccinations through other mechanisms, including quality programs. We encourage individuals to stay up-to-date with their COVID-19 vaccines in accordance with CDC recommendations (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#recommendations>).

Comment: While many commenters supported the COVID-19 vaccination requirements, the majority of commenters stated that CMS did not have the statutory authority to infringe on the personal rights of health care staff to choose vaccination or not. These commenters described the requirements as an overreach of CMS authority and a violation of personal freedoms and bodily autonomy. Several individual commenters expressed concerns that the vaccination requirements may run afoul of certain fundamental medical ethics doctrines around informed consent and freedom from coercion.

Response: We appreciate the feedback from commenters. Although we are withdrawing the health care staff COVID-19 vaccination provisions of the IFC for the reasons discussed throughout this preamble, we disagree with the comments regarding CMS’ statutory authority to issue the rule. In *Biden v. Missouri*, the Supreme Court stayed injunctions prohibiting the rule from going into effect, holding that “the Secretary’s rule falls within the authorities that

²³ <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

²⁴ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

Congress has conferred upon him.”^{25,26} Since that ruling, two plaintiff States voluntarily dismissed challenges to the rule, and Federal courts have dismissed two other cases.^{27,28} We also note that the staff vaccination IFC permitted individual exemptions consistent with applicable Federal laws.

We acknowledge the difficulties that health care workers have faced and continue to face throughout the COVID-19 pandemic. CMS has great appreciation for health care workers and other frontline workers across the world as they have dealt with limited resources and extraordinary demand for their time and services. Due to the changing circumstances of the pandemic previously discussed in this final rule, we are withdrawing the health care staff COVID-19 vaccination provisions of the IFC. In lieu of regulatory requirements and as previously noted, CMS intends to continue supporting and encouraging for health care staff vaccinations through other mechanisms, including its quality programs.

Comment: Many commenters stated that the requirements would contribute to and exacerbate staffing shortages, particularly in rural areas, negatively impacting care and access to care. These commenters expressed concern that the staff vaccination requirements would cause a mass flight of unvaccinated health care workers from the industry. This was of particular concern for entities that provide long-term care services, specifically those facilities located in rural, frontier, and Tribal communities. Some individual commenters who identified themselves as licensed professionals, including but not limited to nurses, stated their intent to resign rather than comply, or that they had coworkers who intended to resign instead of comply. Additionally, some commenters noted that CMS was establishing overly burdensome expectations for already put-upon health care workers. For example, they noted that they were asked to wear personal protective equipment (PPE) if they were not vaccinated even though there were insufficient

²⁵ https://www.supremecourt.gov/opinions/21pdf/21a240_d18e.pdf.

²⁶ <https://www.cms.gov/newsroom/press-releases/statement-cms-administrator-chiquita-brooks-lasure-us-supreme-courts-decision-vaccine-requirements>.

²⁷ *State of Louisiana v. Becerra*, No. 3:21-cv-3970 (W.D. La. Dec. 2, 2022).

²⁸ *Griner v. Biden* 2:22CV149 DAK-DBP (D. Utah Oct. 13, 2022).

supplies, resulting in reuse, and emphasized how they had been directed to continue working to care for patients while ill with COVID-19 themselves due to staffing shortages. Some commenters suggested additional flexibilities in the vaccination requirements, such as the ability to opt-out for philosophical reasons and additional funding in order to help with these potential issues.

Response: We thank commenters and health care workers for their continued dedication throughout the COVID-19 pandemic. Adequate staffing was a concern prior to the pandemic, and we recognize that the COVID-19 PHE simultaneously exacerbated and accelerated those trends. While these trends reflect a confluence of factors, including unprecedented stress, trauma, overwhelming loss associated with death of coworkers and patients (particularly for nurses who typically witness decline and death), and self-isolation or quarantine from families, we also understand commenters' concern that the requirements in the staff vaccination IFC would further add to those shortages.

Available evidence continues to support the notion that staff vaccination requirements have not adversely affected health care staffing.²⁹ Using National Healthcare Safety Network (NHSN) data from June 6, 2021-November 14, 2021, one study showed that State-level COVID-19 vaccine requirements implemented prior to the publication of the IFC did not negatively impact health care staffing levels in those States.³⁰ Specifically, staffing shortages peaked nationally during the Omicron wave, with nearly one in three facilities reporting a shortage in January 2022. Staffing shortage rates have fallen since then, and remained relatively stable through March 2022, even after the implementation of the staff vaccination IFC.³¹ Further, data and analysis, including internal CMS analyses of facility payroll data postdating the

²⁹ See *Biden v. Missouri*, https://www.supremecourt.gov/opinions/21pdf/21a240_d18e.pdf.

³⁰ https://jamanetwork.com/journals/jama-health-forum/fullarticle/2794727?utm_source=For_The_Media&utm_medium=referral&utm_campaign=fim_links&utm_term=072922.

³¹ <https://www.kff.org/coronavirus-covid-19/issue-brief/nursing-facility-staff-vaccinations-boosters-and-shortages-after-vaccination-deadlines-passed/>.

implementation of the staff vaccination IFC, suggest that the rule did not have a negative impact on health care staffing.

We acknowledge that staffing concerns remain throughout the health care system; however, we do not anticipate that the withdrawal of the health care staff COVID-19 vaccination requirements will meaningfully affect current challenges in staff recruitment and retention.

Comment: Many commenters shared their belief that vaccines are unsafe and that they contain dangerous or potentially dangerous chemicals. These commenters also expressed concerns that Emergency Use Authorizations (EUAs) issued by the Food and Drug Administration (FDA) do not assure safety, because of the minimal length of development time. Some commenters noted that CMS or the employer should be liable for adverse effects of vaccination and that this should include lost wages in event of illness or death. Some commenters referenced the Vaccine Adverse Effect Response System (VAERS), noting that there have been nearly one million reported cases of adverse reactions to the various COVID-19 vaccines. These commenters expressed their disagreement with COVID-19 vaccination requirements based on these VAERS reports. Some commenters also referenced the Nuremberg Code, which prohibits adherents from performing medical experimentation in unwilling patients. These commenters stated a belief that the vaccines are truly experimental.

Response: While we are withdrawing the staff vaccination requirements given changes in public-health conditions described throughout this preamble, we emphasize that COVID-19 vaccines have consistently been shown to be safe and effective. As of March 2023, more than 672 million doses of COVID-19 vaccine have been given in the United States under the most intense safety monitoring in US history. That monitoring by CDC, FDA, and other Federal agencies continues to demonstrate that COVID-19 vaccines are safe and effective.³² Moreover, efforts to speed the vaccine development process have not sacrificed scientific standards,

³² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,safety%20monitoring%20in%20US%20history>.

integrity of the vaccine review process, or safety.³³ Prior to issuance of an EUA, the original COVID-19 vaccines were evaluated in tens of thousands of study participants to generate the scientific data and other information needed to determine the vaccine's safety and effectiveness.

Comments regarding liability for adverse effects of vaccination or lost wages are outside the scope of this rule. We refer readers to the Department of Labor for issues regarding workplace injury and compensation.³⁴ We also refer readers to the Countermeasures Injury Compensation Program, which provides compensation for covered serious injuries or deaths that occur as the result of the administration or use of certain countermeasures and the National Vaccine Injury Compensation Program, which provides compensation to people found to be injured by certain vaccines.^{35,36,37}

Comment: Many commenters stated a belief that vaccines are ineffective. They shared how the incidence of COVID-19 infections among vaccinated individuals is high. These commenters also noted that this rule would be ineffective, because it did not apply to patients and visitors.

Response: We acknowledge that COVID-19 vaccines will not prevent symptomatic infection in all vaccinated individuals; however, COVID-19 vaccines are highly effective in preventing serious illness, hospitalization, and death.

As we discussed in the staff vaccination IFC, we believe it would be overly burdensome to require that facilities ensure COVID-19 vaccination for all individuals who enter (patients, visitors, mail carriers, etc.). However, while facilities are not required to ensure vaccination status of every individual, they may choose to extend COVID-19 vaccination requirements

³³ <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained#:~:text=Under%20an%20EUA%2C%20FDA%20may,are%20no%20adequate%2C%20approved%2C%20and.>

³⁴ <https://www.fiercehealthcare.com/hospitals/supreme-court-vaccine-covid-19-healthcare-upholds-hhs-vaccine-requirement-for-healthcare#:~:text=Supreme%20Court%20upholds%20HHS%20vaccine,large%20employer%20mandate%20%7C%20Fierce%20Healthcare.>

³⁵ <https://www.hrsa.gov/cicp.>

³⁶ <https://www.benefits.gov/benefit/641.>

³⁷ <https://www.hrsa.gov/vaccine-compensation/about.>

beyond those persons that we consider to be “staff” as defined in IFC. We did not prohibit such extensions and encouraged facilities to require COVID-19 vaccination for these individuals as reasonably feasible. We strongly encourage facilities, when the opportunity exists and resources allow, to facilitate the vaccination of all individuals who provide services infrequently or provide educational opportunities about vaccination for those individuals. Further, as previously discussed, CMS intends to continue support and encouragement for health care staff vaccinations through quality measurement programs.

Comment: Some commenters stated that vaccines contain fetal stem cells, the use of which conflicts with their religious beliefs. Other commenters indicated that contracted physicians with privileges are not covered under Title VII or ADA; therefore, they are unable to request religious exemptions. Industry, civil society groups, and individual commenters sought clarification regarding religious, medical, and administrative exceptions to the vaccination requirements. Some commenters stated that it would be helpful for CMS to create a standard on exemption requirements that would be broadly applicable nationwide. Some commenters asked for clarification on exemption requirements and recommended that CMS promulgate guidance. Other commenters noted that we should consider referencing the Equal Employment Opportunity Commission or similar nondiscrimination guidance (such as the Americans with Disabilities Act) in order to address these public concerns.

Response: While we are withdrawing the staff vaccination requirements in this final rule, we note that the IFC required facilities to have policies and procedures regarding exemptions as required by civil rights and disability laws.

Comment: Some commenters suggested that alternatives to vaccination be added to the requirements. These commenters emphasized that routine testing of staff for SARS-CoV-2 and use of PPE should be permitted in lieu of vaccination. Some commenters noted the ongoing mitigation efforts involving COVID-19 testing and PPE use, as well as required source controls which have improved over the course of the PHE. Some commenters suggested that CMS

provide for additional flexibility by “grandfathering in” some of the vaccination requirements already in place among certain health systems. Some commenters suggested additional educational outreach, especially among communities with lower trust in the health care system, as well as an understanding of the logistical issues preventing prompt implementation of the requirements in the staff vaccination IFC at certain facilities. Other commenters supported additional educational outreach, time-limited testing options, and flexibility for “good-faith” efforts for facilities as they work toward compliance with the rule.

Response: We thank commenters for their continued efforts in practicing complementary mitigation measures, especially at times when resources have been limited and as the pandemic continues to evolve.

Our intention in issuing the staff vaccination IFC was to establish a set of requirements for all applicable facility types consistent with CDC recommendations in place at the time to assure patient health and safety. Since the onset of the PHE, the context in which people apply these preventive layers has changed. As the immediate impacts of the COVID-19 pandemic continue to evolve, so too does informed guidance, recommendations, and regulation. In the fall of 2021, circumstances required that CMS issue the IFC to protect the health and safety of patients. Current circumstances show that the IFC was effective in increasing rates of COVID-19 vaccination among health care staff and indicate that the need for such regulatory requirements has passed. We continue to explore different approaches to support and incentivize the use of effective combinations of preventive layers in particular circumstances and the best, most flexible way to support their application.

CMS and other HHS agencies continue to engage in infection prevention and control and vaccine education efforts. Additionally, CMS continues to host stakeholder engagement calls to address ongoing concerns and questions.³⁸ CMS also continues to engage with key stakeholders in order to develop culturally-competent and person-centered guidance and resources to ensure

³⁸ <https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-resources>.

that populations with unique needs or concerns are addressed and mitigated. Lastly, enforcement discretion is not within the scope of these regulations and is rather addressed in subregulatory guidance, which CMS continues to publish and release.³⁹ We encourage individuals to continue to follow CDC recommendations pertaining to infection prevention and control practices, and we note that while this final rule ends CMS's requirements regarding staff vaccination, it does not prohibit employers or states from initiating or maintaining their own vaccination requirements for health care staff. We also continue to support health care staff vaccinations through quality measurement programs.

Comment: Some commenters stated that individuals with a prior COVID-19 infection should be exempt due to natural immunity. Many of these commenters claimed that they still had high levels of antibodies against COVID-19 in their most recent blood tests, and they questioned the necessity of vaccination, at least for as long as their antibody levels remain comparable to those who are vaccinated.

Response: We acknowledge that previous COVID-19 infection may also contribute to protection against subsequent infection and associated severe, critical, or fatal COVID-19.⁴⁰ However, this does not mean infection-induced immunity can or should be substituted for vaccination. Exceptions based on infection-induced immunity are also challenging to apply and enforce fairly, as verification of a health care worker's prior infection or antibody levels may not be possible in all cases. Vaccination remains the safest option for acquiring immunity to COVID-19, particularly when the risks associated with vaccination are compared with well-known significant short and long-term consequences of COVID-19, which can include organ damage affecting the heart, kidneys, skin, and brain, as well as fatigue, shortness of breath, loss of smell, and muscle aches.^{41,42,43} Additionally, people who have had COVID-19 are more likely

³⁹ <https://www.cms.gov/covidvax>.

⁴⁰ <https://www.cdc.gov/coronavirus/2019-ncov/your-health/reinfection.html>.

⁴¹ [https://www.thelancet.com/journals/lanam/article/PIIS2667-193X\(22\)00059-X/fulltext](https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(22)00059-X/fulltext).

⁴² <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351#:~:text=Why%20does%20COVID%2D19%20cause,immune%20system%20can%20also%20happen.>

⁴³ <https://www.nhs.uk/conditions/coronavirus-covid-19/long-term-effects-of-coronavirus-long-covid/>.

to develop new health conditions such as diabetes, heart conditions, blood clots, or neurological conditions compared with people who have not had COVID-19.⁴⁴

Comment: Some commenters stated that COVID-19 is not a public health emergency and that the data upon which guidelines are issued are flawed, alleging inaccurate and inflated death counts. Commenters also pointed out that the overwhelming majority of infected individuals recover, unvaccinated individuals do not all become severely ill, and there are treatments available that should be encouraged and available for use (for example, some commenters stated beliefs that Ivermectin or Vitamin D and other pharmaceutical and nonpharmaceutical products are effective treatments for COVID-19).

Response: While rates of infection, illness, and hospitalization have significantly declined, COVID-19 remains a public health challenge throughout the world. As discussed in section I. of this final rule, the WHO declared the COVID-19 outbreak an international public health emergency in January 2020 and a pandemic in March 2020. Likewise, a COVID-19 PHE declaration for the United States was made by the Secretary in January 2020, the President of the United States declared COVID-19 a pandemic in March 2020, and the Secretary has sustained a PHE declaration since January 2020 with the final renewal occurring on February 9, 2023.⁴⁵ In September 2021, COVID-19 related deaths in the U.S. surpassed the number of deaths from the 1918 influenza pandemic.⁴⁶ According to the CDC COVID Data Tracker, over 1.1 million COVID-19 deaths have been reported in the United States to date, whereas it is estimated that 675,000 American deaths occurred during the 1918 influenza pandemic.^{47,48}

Research also suggests that reported deaths associated with COVID-19 in the United States have been undercounted, not overcounted, since the start of the pandemic. These undercounts may be attributed to several factors, including that testing availability and criteria

⁴⁴ <https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html>.

⁴⁵ <https://aspr.hhs.gov/legal/PHE/Pages/default.aspx>.

⁴⁶ <https://www.smithsonianmag.com/smart-news/the-covid-19-pandemic-is-considered-the-deadliest-in-american-history-as-death-toll-surpasses-1918-estimates-180978748/>.

⁴⁷ <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

⁴⁸ <https://www.cdc.gov/flu/pandemic-resources/1918-commemoration/1918-pandemic-history.htm>.

may have caused many cases to go unrecognized; COVID-19 may affect many body systems, and thus may not always be recognized as a cause of death; and COVID-19 may amplify pre-existing health conditions leading to death, but not be recognized as the cause of death by the medical certifier.⁴⁹

We acknowledge that most individuals are fortunate enough to recover from COVID-19. However, many individuals are not fortunate enough to recover and many individuals die or experience symptoms of long COVID, with older adults facing the highest risk of becoming very sick from COVID-19.

We are also grateful for the development of effective antiviral treatments, including Remdesivir (Veklury), nirmatrelvir co-packaged with ritonavir (Paxlovid), and molnupiravir (Lagevrio).^{50,51} These drugs have also undergone rigorous testing. We note that the evolution of COVID-19 continues to present challenges to the development of both preventative drugs, including vaccines, and therapeutic treatments. It is important that more individuals be educated about these drugs in order for them to make informed decisions about their health and treatment options.

Some medications mentioned by commenters, such as Ivermectin and vitamin D, are not evidence-based treatments for COVID-19. The FDA has not authorized or approved Ivermectin for use in preventing or treating COVID-19 in humans or animals. Ivermectin is approved for human use to treat infections caused by some parasitic worms and head lice and skin conditions like rosacea. Currently available data do not show that Ivermectin is effective against COVID-19 and taking large doses of Ivermectin is dangerous.⁵² There is also insufficient evidence for the use of vitamin D for the prevention or treatment of COVID-19.⁵³ Individuals who are

⁴⁹ <https://www.cdc.gov/nchs/covid19/faq.htm>.

⁵⁰ <https://www.covid19treatmentguidelines.nih.gov/therapies/antivirals-including-antibody-products/summary-recommendations/>.

⁵¹ <https://www.fda.gov/media/155049/download>.

⁵² <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>.

⁵³ <https://www.covid19treatmentguidelines.nih.gov/therapies/supplements/vitamin-d/>.

considering taking these medications as a treatment for COVID-19 should consult with their care team.

Comment: Some commenters shared their belief that it is unprecedented to mandate COVID-19 vaccines when there are other existing vaccines that are more effective that are not mandated (that is, Hepatitis B, influenza, pneumococcal).

Response: We thank commenters for recognizing the efficacy of certain vaccines, like the Hepatitis B, influenza, and pneumococcal vaccines. While we do not want to minimize the severity of these diseases, they were not the cause of the PHE declared at the time CMS issued the IFC. We also note that the regulation is not a government vaccine mandate placed on individuals but rather a Medicare and Medicaid funding condition for certain health care facilities that participate in either or both of those programs. As discussed in section H. of the staff vaccination IFC, many health care workers must already comply with employer or State government vaccination requirements (influenza, hepatitis B) or OSHA guidelines and are also required to complete screening procedures, such as tuberculosis screening. Additionally, many of these individuals met State and local vaccination requirements in order to attend school to complete the necessary education to be eligible for health care positions. While historically CMS has not required any health care staff vaccinations, we have established, maintained, and updated extensive health and safety requirements as part of the Conditions of Participation and Conditions for Coverage for Medicare- and Medicaid-certified providers and suppliers. These requirements largely focus on infection prevention and control standards, as we aim to protect the health and safety of patients, residents, clients, and participants.

The transition CMS is making now, to make COVID-19 policies more like those for other communicable diseases, reflects the ongoing evolution of epidemiological and clinical circumstances; it does not imply that our issuance of the staff vaccination IFC was invalid or that CMS could not take such steps again in the future, if circumstances warrant. While we are withdrawing the provisions of the staff vaccination IFC, as previously noted, we intend to

continue to support and encourage COVID-19 vaccination through our quality reporting and value-based incentive programs. CMS collaborated with the CDC to develop quality measures for both patient and health care vaccination to be used in appropriate quality programs. CMS included patient and health care personnel vaccination quality measures on the Measures Under Consideration (MUC) List issued on December 1, 2022.^{54,55}

Comment: Some commenters mistakenly believed this IFC was OSHA’s rule, “COVID-19 Vaccination and Testing; Emergency Temporary Standard” (86 FR 61402) (also published November 5, 2021), which intended to require vaccination for employers with 100+ employees and addressed the emergency temporary standard (ETS) in comments submitted to CMS.⁵⁶

Response: The requirements in the staff vaccination IFC apply to only the Medicare- and Medicaid-certified providers and suppliers listed in the IFC. The IFC does not directly apply to other employers or entities, including other health care entities, such as physician offices, which are not regulated by CMS. Most States have separate licensing requirements for health care staff and health care providers that would be applicable to physician office staff and other staff in small health care entities that are not subject to vaccination requirements under this IFC. Within the IFC, we briefly discussed the OSHA IFC, “Occupational Exposure to COVID-19; Emergency Temporary Standard” (86 FR 32376, June 21, 2021), that was applicable to health care settings at the time of publication, including but not limited to the providers and suppliers who must comply with the staff vaccination IFC, because the OSHA ETS and the IFC had complementary requirements.⁵⁷ Of note, OSHA did withdraw the vaccination and testing ETS,

⁵⁴ <https://mmshub.cms.gov/sites/default/files/2022-MUC-List-Overview.pdf>.

⁵⁵ <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

⁵⁶ <https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard>.

⁵⁷ <https://www.federalregister.gov/documents/2021/06/21/2021-12428/occupational-exposure-to-covid-19-emergency-temporary-standard>.

effective January 26, 2022.^{58,59} For questions about OSHA laws, regulations, or rulemaking activities, we refer commenters to OSHA.⁶⁰

Comment: A few commenters noted that this rule was promulgated prior to consultation with Tribal entities, which they asserted is a violation of Executive Order (E.O.) 13175. Several organizations noted that Tribes believed that their treaty rights may have been violated by the promulgation of the rule. One commenter noted that they understand that the rule may be appropriate for non-Indian health providers but indicated that the Tribes they represent believe that it is not currently clear how the regulation would apply to those facilities that provide health care services to the American Indian and Alaska Native population. These commenters stated that CMS failed to consult with Tribes in accordance with the usual Indian consultation guidance. The commenters suggested that CMS extend the comment period and improve the consultative relationship between Tribal entities and CMS so that the perceived disregard for Tribal sovereignty does not happen again.

Response: We thank the Tribes for their continued partnership with CMS. We recognize that American Indians and Alaska Natives (AI/AN) face unique health care needs and have been disproportionately impacted by COVID-19.^{61,62} These commenters are incorrect in their assumption of a violation of E.O. 13175. That E.O. only applies to actions that “have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” The staff vaccination IFC, like almost all CMS rules, has none of these effects. This IFC applied only to certain health care providers and suppliers who voluntarily enrolled in the Medicare and Medicaid programs. Its provisions made no distinctions

⁵⁸ <https://www.osha.gov/coronavirus/ets2>.

⁵⁹ 87 FR 3928, January 26, 2022 (<https://www.federalregister.gov/documents/2022/01/26/2022-01532/covid-19-vaccination-and-testing-emergency-temporary-standard>).

⁶⁰ <https://www.osha.gov/laws-regs>.

⁶¹ <https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-cases-and-deaths-by-race-ethnicity-current-data-and-changes-over-time/>.

⁶² <https://www.cdc.gov/mmwr/volumes/71/wr/mm7122a2.htm>.

as to ownership status of any facility, whether owned or administered by a private organization, State or local government, or tribe. Furthermore, the commenters identified no specific government-to-government effects from the rulemaking that would adversely affect tribes. CMS continues to engage with external stakeholders and strives towards providing, supporting, and fostering culturally-competent and person-centered care for these populations.

Comment: Some provider groups asked for clarification or additional guidance on what would or would not be acceptable in terms of employer enforcement so that they could stay within the bounds of State privacy laws. For example, a large medical center noted concerns about their ability to comply with both the IFC and a State law that explicitly prevented employers from requiring COVID-19 vaccinations as a condition of employment.

Response: As discussed in the staff vaccination IFC, we understand that some States and localities have established laws that would seem to prevent Medicare- and Medicaid-certified providers and suppliers from complying with the requirements of this IFC. While the requirements outlined in the staff vaccination IFC remain in force, we intend, consistent with the Supremacy Clause of the United States Constitution, that this nationwide regulation preempts all conflicting State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers. However, as previously noted, we are withdrawing the health care staff COVID-19 vaccination provisions.

Comment: Some commenters noted that the COVID-19 staff vaccination requirements placed an undue burden on facilities. These commenters stated that it would be overly burdensome to manage individual requests for exemption either due to religious beliefs or clinical contraindications to receiving the vaccine. They also noted that it would be resource-intensive to comply with the vaccination requirements that included contracted staff.

Response: As noted in the preamble of the IFC, we made efforts to mitigate the burden on providers by not requiring that each provider and supplier ensure COVID-19 vaccination for all individuals who entered the facility or setting of care, because we believed such a requirement

would be overly burdensome. Moreover, CMS did not require that staff who functioned in a fully remote capacity be vaccinated for COVID-19 if they did not physically enter the building or interact with patients or other staff. Experience since the publication of the staff vaccination IFC shows that facilities could, indeed, meet these requirements. When implementing these requirements, CMS ensured there was a reasonable balance between burden and the need for celerity to realize health and safety benefits.

Comment: Many commenters noted that the IFC's definition of "fully vaccinated" was confusing and questioned whether booster doses would or should be included in the definition and required going forward. Some of these commenters shared that there was confusion in the messaging coming from CMS regarding boosters and potential discrepancies between the IFC and contemporary information aids coming from other parts of the executive branch. Likewise, some commenters noted that the CDC did not include boosters in its definition of "fully vaccinated" at the time that the rule was issued. Other commenters recommended that CMS recognize the importance of booster shots and consider including boosters in the definition of "fully vaccinated" once the CDC updates its guidance. Some commenters also pointed to research that suggests the importance of boosters in maintaining immunity over time. Several individual commenters stated that the need for boosters would make the rule impracticable or that it proved the ineffectiveness of the vaccines.

Response: Like the SARS-COV-2 virus itself, the science of preventing and treating COVID-19 and the tools available to prevent and treat it continue to evolve. Thus, the recommendations and guidance have similarly changed as well. Currently, CDC recommends that people ages 6 months and older receive at least 1 bivalent mRNA COVID-19 vaccine. The number of recommended bivalent doses varies by age, vaccine, previous COVID-19 vaccines received, and the presence of moderate or severe immune compromise. As discussed elsewhere in this rule, CMS now believes that other levers available to us (for example, quality measures) offer the most effective means to balance a need for flexibility, encourage HCP vaccination, and

protect patient safety in the post-PHE phase of COVID-19. In addition, as of March 30, 2023, 90.5 percent of counties, districts, or territories in the United States had a low community level of COVID-19. Further, as of March 29, 2023, the current 7-day average of weekly new cases decreased 9.2 percent compared with the previous 7-day average.⁶³ Therefore, we are withdrawing the health care staff COVID-19 vaccination provisions.

Comment: Many commenters requested clarification as to which facility types the rule applies. Individuals associated with Emergency Medical Services (EMS) and ambulance services requested additional guidance on how they fit within the rule, because they were not among the facility types listed in the rule. Other groups, particularly in long-term care, asked whether contractors (a one-off or incidental plumber, or a fully remote administrative staff worker, for example) would be required to be vaccinated in order for the facility to be considered in compliance. Some commenters recommended that CMS align the definition of “staff” with previous LTC facility testing rules as a means of reducing confusion and as a means of helping those facilities align their current vaccine requirements with those required under the rule.

Response: We are withdrawing the health care staff COVID-19 vaccination provisions. We strongly encourage facilities, when the opportunity exists and resources allow, to facilitate the vaccination and education of all individuals who provide services infrequently or frequently.

Comment: Some commenters suggested that new anti-viral treatments may become more important as tools once they become commercially available. They asked that CMS include guidance in this rule, or issue another rule which would clarify some of the different payment aspects of these treatments and more.

Response: We recognize and acknowledge the important role of new treatment therapies that have recently become available, as previously discussed in this rule. However, payment for these treatments is outside the scope of this rule. We emphasize the importance of vaccination,

⁶³ https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/033123.html#:~:text=COVID%2D19%20Community%20Levels*,with%20a%20low%20Community%20Level.

as access to these new therapies may vary. Further, these therapies do not replace the preventive benefits of vaccination.

Final Decision: After inspection of public comments on the health care staff vaccination requirements and in consideration of the factors discussed throughout this rule, we are withdrawing the health care staff COVID-19 vaccination provisions. This final rule addresses CMS' statutory responsibility to implement regulations necessary to protect the health and safety of patients while demonstrating our commitment to approaches that reflect evolving information.

B. COVID-19 Vaccine “Educate and Offer” Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff (§§ 483.80(d), 483.430(f), 483.460(a)(4))

In response to the educate and offer IFC, we received 68 public comments. Twenty-six of these comments addressed the “educate and offer” provisions, sharing support for these requirements due to the increased risk of infection and complications for LTC residents and ICF-IID clients due to their medical conditions and residence in congregate care settings. Public commenters also addressed the reporting requirements, which we addressed in the CY 2022 Home Health Prospective Payment System final rule (86 FR 62240, 62392).

Comment: The majority of commenters emphasized that residents of LTC facilities and clients of ICFs-IID are among the most susceptible to negative outcomes related to COVID-19 due to their medical conditions. These commenters noted that the residents and clients were at high risk for exposure, infection, complication, and death.

Response: We thank commenters for recognizing the gravity of the COVID-19 pandemic and their appreciation for resident and client health and safety. We believe that all LTC Facility residents, ICF-IID clients, and the staff who care for them, should be provided with ongoing education about, and access to, vaccination against COVID-19. Further, we believe that entities responsible for the care of residents and clients of LTC facilities and ICF-IIDs must proactively pursue access to COVID-19 vaccination on behalf of their residents and clients, who often face challenges to independently accessing the vaccine, including mobility limitations, cognitive

impairments, and other conditions. To support ongoing access to vaccinations for COVID-19, we are finalizing the provisions at §§ 483.80(d)(3), 483.430(f), and 483.460(a)(4) for LTC facilities and ICF-IIDs.

Comment: Some commenters stated that communicating the pros, cons, and side effects of vaccination in a meaningful way to LTC facility residents was challenging and recommended that CMS provide additional guidance and standardized education materials for use.

Response: We acknowledge that it can be challenging to convey this information clearly as the COVID-19 pandemic continues to evolve and new treatments and vaccines become available. Vaccination remains one of the most important methods to help prevent severe COVID-19, especially as individuals living and working in congregate living settings may have challenges with physical distancing and other preventive measures such as mask use. While it can be challenging to convey vaccine information clearly, this is especially important, as many ICF-IID clients have multiple chronic conditions and psychiatric conditions in addition to their intellectual disability, and many LTC Facility residents experience impaired mental status, which can impact a client's and resident's understanding or acceptance of the need for vaccination. Vaccine education allows for residents, clients, and their caregivers to be informed participants in their care and allows them to make the most appropriate decisions for themselves. Furthermore, CDC and FDA have developed a variety of clinical educational and training resources for health care professionals related to COVID-19 vaccines, and CMS recommends that nurses and other clinicians work with their LTC Facility's or ICF-IID's Medical Director and use CDC and FDA resources as sources of information for their vaccination education initiatives.⁶⁴ We acknowledge and thank the many CMS-certified ICF-IIDs and LTC facilities that are educating staff, residents, and clients, and are attempting to participate in vaccination programs. However, participation in these efforts is not universal, and we are concerned that many individuals are not receiving these important preventative care services. Because resident

⁶⁴ <https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships/administrators-managers.html>.

and client safety are of the utmost importance, we are finalizing the education requirements for LTC facilities at § 483.80(d)(3) and ICF-IIDs at §§ 483.430(f) and 483.460(a)(4).

Comment: Several commenters expressed burden concerns due to high staff turnover rates, which have increased the amount of time needed to provide education and to offer the vaccine to staff.

Response: We thank the staff for their hard work in complying with these requirements. We recognize that health care organizations have historically experienced staffing shortages and that this has been exacerbated by the pandemic, as discussed in section I. of the staff vaccination IFC. In addition to the previously mentioned resources available from CDC and FDA, CMS funds a network of Quality Improvement Organizations (QIOs),⁶⁵ which aim to improve the quality of care delivered to people with Medicare. Specifically, QIOs may provide assistance to Medicare beneficiaries by targeting small, low-performing, and rural Medicare-certified facilities most in need of assistance, and those that have low COVID-19 vaccination rates; disseminating accurate information related to access to COVID-19 vaccines to facilities; educating residents and staff on the benefits and risks of COVID-19 vaccination; understanding nursing home leadership perspectives and assist them in developing a plan to increase COVID-19 vaccination rates among residents and staff.

Ensuring that all LTC Facility residents, ICF-IID clients, and the staff who care for them are provided with ongoing opportunities to receive vaccination against COVID-19 is critical to ensuring that populations at higher risk of infection continue to be prioritized and receive timely preventive care during the COVID-19 pandemic. In the interest of health and safety for LTC facility residents and ICF-IID clients, and of staff in these settings, we are finalizing the provisions at § 483.80(d)(3) for LTC facilities and §§ 483.430(f) and 483.460(a)(4) for ICF-IIDs.

Comment: Some commenters reported that it was difficult to identify the individuals that met the definition of “staff,” and therefore, were subject to the requirements.

⁶⁵ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs>.

Response: The “educate and offer” provisions were written in a manner that allows for flexibility by covering a broad set of residential care entities. Additionally, since this IFC was initially published, CMS and other agencies across HHS have released additional guidance in an effort to address some of these questions and concerns about how to comply with these requirements.⁶⁶ Furthermore, CMS uses existing lines of communication with stakeholders in an effort to address some of these questions and concerns. Currently, CMS considers LTC facility and ICF-IID staff (regardless of whether there is a so-called “W-2” relationship) to be those who work in the facility on a regular basis (that is, at least once a week). We note that this includes those individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. LTC facilities and ICF-IIDs are not required to educate and offer vaccination to individuals who provide services less frequently, but they may choose to extend such efforts to them. We strongly encourage facilities, when the opportunity exists and resources allow, to provide education and vaccination to all individuals who provide services less frequently. A better understanding of the value of vaccination may allow staff to appropriately educate residents and their family members about the benefits of accepting the vaccine. Therefore, we are finalizing the requirements at §§ 483.80(d)(3), 483.430(f), and 483.460(a)(4).

Comment: A few commenters suggested that CMS add provisions for paid time off for staff to receive the vaccine and recover from side effects.

Response: We recognize commenters’ concerns; however, CMS does not have the statutory authority to regulate paid time off for health care employees, and this falls outside the scope of this final rule.

Final Decision: After consideration of the public comments we received on the educate and offer requirements, we are finalizing the requirements at § 483.80(d)(3) for LTC facilities and at §§ 483.430(f) and 483.460(a)(4) for ICF-IIDs, as established by the educate and offer IFC

⁶⁶ <https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-resources>.

and amended by the staff vaccination IFC. The “educate and offer” requirements support our responsibility to protect and ensure the health and safety of residents and clients by enforcing the standards required to help each resident and client attain or maintain their highest level of well-being. Sections 1819(d)(3)(B) and 1919(d)(3) of the Act require that a facility must establish an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. We believe that the educate and offer requirements comply with these statutory requirements. We believe that this action strengthens our response to the COVID-19 pandemic and protects the health and safety of nursing home residents, ICF-IID clients, and their staff.

C. COVID-19 Testing Requirement for LTC Facilities § 483.80(h)

In response to this IFC we received approximately 169 comments, of which about 150 addressed the COVID-19 testing requirements for LTC facilities’ staff and residents.

Comment: Some comments acknowledged that testing for COVID-19 is important for preventing the disease from entering nursing homes, detecting cases quickly, and stopping the transmission to additional residents and staff.

Response: We thank commenters for sharing their understanding of the importance of testing for COVID-19. While many new treatments and vaccines are now available, and we are deleting the expired testing requirements, we continue to emphasize the importance of practicing preventative measures in order to mitigate the spread of COVID-19.

Comment: Many commenters discussed the need for accurate data for contact tracing and in order to understand the future trajectory of the COVID-19 virus. However, most comments expressed belief that the community infection rate is not an accurate method for calculating how often COVID-19 testing should be conducted. Several of these commenters explained that a high community rate may be skewed by isolated populations, such as incarcerated individuals or college and university students. Commenters noted that higher infection rates in these populations resulted in being required to test staff and residents twice weekly, which they

believed did not yield additional information. A few of these commenters also noted that many of the LTC staff do not reside in the same county as the facility and thus are not living in a county with a similarly high community infection rate; therefore, they should not be subject to more frequent testing requirements.

Response: We thank commenters for recognizing the importance of collecting accurate data and its use for informing an appropriate pandemic response. It is important for data to be measured and reported in a standardized manner. This allows for public health officials to compare disease occurrence across different populations in order to make informed policy decisions and to better understand the virus and its impact on health outcomes. We recognize that some locations, like prisons or college and university campuses, may represent “hot spots.” However, these populations are not truly isolated, and one may not presume that the SARS-CoV-2 virus will not spread to other populations or locations.

Further, frequent testing for COVID-19 remains an important tool for mitigating the transmission of the virus. In some instances, an individual may test when the viral load is not high enough to be found on a test and the test result is negative. But this same individual may test again in the same week and receive a positive test result. Additionally, some people may test negative on an antigen test but positive on a PCR test. This means that they do have COVID-19, but their viral load is too low to result in a positive antigen test.⁶⁷ We recognize that many staff do not reside in the same county as the LTC facility at which they are employed. However, this does not negate the value of testing. While these individuals may be less likely to be exposed to the virus in the county in which they reside, the risk of exposure is not eliminated. In addition, because of the highly contagious nature of the SARS-CoV-2 virus, the transmission levels in the county in which they reside may increase significantly, subsequently increasing their risk of exposure.

⁶⁷ <https://publichealthmdc.com/blog/did-you-test-negative-when-sick-or-exposed-to-covid-heres-what-it-means#:~:text=If%20you%20test%20negative%20soon,be%20found%20on%20a%20test.>

Comment: The majority of comments stressed how these new testing requirements are diverting resources and adding an additional burden to the staff, who are already strained by the staffing shortage. These comments also discussed how it is challenging to comply with the requirements due to limited availability of PPE. Most of these comments emphasize that the frequent testing takes away valuable time from resident care and socialization, which is critical at a time when residents are not able to see their families. Many commenters also reported that the time frame to report test results was too limited and requested a 72-hour window to report test results. These comments discussed how it is challenging to comply with this requirement due to the increased turnaround time to receive results and the limited number of staff members.

Response: We share sympathy for residents and their family members who were not able to gather in person. We also thank LTC facility staff and health care workers for their continued commitment to providing care for residents. Testing for COVID-19 helps to mitigate the transmission of the virus and thus improves patient outcomes and opportunities for socialization. As discussed in the LTC facility testing IFC, we note that there are many different tests available, and facilities have the flexibility and discretion to select the test that best suits their needs so long as the tests are conducted in accordance with nationally recognized standards and meet the response time for the test results as specified by the Secretary. In addition, the CDC has continued to update its guidance regarding infection control at https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Flong-term-care.html. Further, the CDC has published guidance on how to optimize PPE at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>.

Comment: Several commenters expressed gratitude for the ability to access point-of-care (POC) testing supplies and equipment, but most of these commenters found it to be unreliable and shared that it frequently produced false positive results. These commenters expressed that this blanket approach may not be appropriate for all LTC facilities and suggested that the testing

of staff should be reduced in order to appropriately allocate limited and costly testing supplies and resources. A few comments appealed for permission to utilize pool testing methods for the routine testing of all staff and to focus routine staff testing on those who have the greatest risk of exposure and transmission, such as those who have direct contact with patients. For example, commenters found it unreasonable for a staff member that works in the billing office--who has no face-to-face contact with residents or with staff who provide direct care to residents--to be tested weekly.

Response: We acknowledge that at the time of publication of this IFC, PPE and COVID-19 tests were limited, and we commend staff and health care workers for their diligence working through these challenges. We also recognize the challenges of conducting testing and discuss in the LTC testing IFC that because COVID-19 was newly discovered, the standards of practice for testing for the virus may continue to change or evolve. Additionally, the CDC provides guidance on proper specimen collection at <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html> and <https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>. This rule does not address the manner in which tests are conducted, so long as they are conducted in a manner that is consistent with current professional standards of practice. As such, this comment regarding pool testing methods is not within the scope of the rule.

Readers may find more information regarding pooled testing at https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html#anchor_1625241118971.

Comment: The majority of commenters discussed the financial burden of the COVID-19 testing requirements and noted that this burden was unsustainable considering the staffing shortages and economic impacts of the PHE. Some comments highlighted that PCR tests cost about \$130 and that testing costs accumulate quickly. For example, several commenters shared that they were spending upwards of \$28,000 per month on testing, in addition to their fixed costs. Due to the financial burden, a significant number of comments indicated that the testing

requirements should be accompanied by additional funding and bureaucratic support. Other comments suggested streamlining funding to LTC facilities in areas with greater prevalence of COVID-19.

Response: We recognize that the COVID-19 pandemic has strained the economy and created many challenges. Additional funding and bureaucratic support are not within the scope of this final rule. The CDC has also released guidance for health care facilities that are expecting or experience staffing shortages due to COVID-19 and provides recommendations on mitigation strategies and contingency strategies at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html>.

Final Decision: After evaluation of public comments on the COVID-19 testing requirements for residents and staff of LTC facilities, and in light of their applicability ending with the end of the COVID-19 PHE, we are revising the CFR at § 483.80(h) to remove the expired text. As previously discussed, CMS encourages ongoing COVID-19 mitigation measures through its quality reporting and value-based incentive programs in the near future.

IV. Provisions of the Final Regulation

In this section, CMS discusses the requirements in this final rule. In section IV.A. of this final rule, we discuss the withdrawal of regulations pertaining to COVID-19 vaccination of health care staff. We then discuss final regulations for LTC facilities and ICFs-IID to provide COVID-19 vaccine education and offer vaccination to residents, clients, and staff in section IV.B. of this final rule. Finally, we discuss the deletion of the expired COVID-19 testing requirements of staff and residents for LTC facilities.

A. Omnibus COVID-19 Health Care Staff Vaccination

COVID-19 is a novel disease caused by an unpredictable and nimble virus, SARS-CoV-2. CMS implemented the staff vaccination requirements in the IFC to assure health and safety during a PHE declaration. However, circumstances surrounding COVID-19 continue to evolve and CMS has evaluated its policies pertaining to COVID-19 on an ongoing basis. CMS

continues to recognize that vaccines are important for preventing severe illnesses and promoting public health and that the incidence of severe COVID-19 has declined significantly since the IFC was issued. We believe that using quality programs to promote vaccination is an approach more consistent with the current nature of SARS-CoV-2 (that is, frequent mutation, potentially necessitating new vaccines), and that it can now be treated more like other harmful but not necessarily emergent respiratory viruses like influenza. Accordingly, we are withdrawing from the CFR the requirements regarding COVID-19 vaccination of health care staff as established under the staff vaccination IFC. As discussed in section I.B. of this final rule, CMS intends to encourage ongoing COVID-19 vaccination through other mechanisms, including its quality reporting and value-based incentive programs. CMS continues to develop and refine quality measures for both patient and health care personnel vaccination to be used in appropriate quality programs and included patient and health care personnel vaccination quality measures, such as those seen on the MUC list issued on December 1, 2022. In addition to quality measurement, CMS continues to provide assistance and education through CMS-funded entities (including QIOs, Hospital Quality Initiatives (HQICs), and ESRD Networks), as well as to work with Federal, State, local, and industry partners who can also provide education and technical support.

The withdrawal of the COVID-19 staff vaccination requirements from the CoPs, CfCs, and requirements should not be construed as a diminution of CMS support for vaccination or for facilities to require staff vaccination. Moreover, withdrawal of the requirements from the CoPs, CfCs, and requirements for LTC facilities does not prohibit facilities from requiring staff vaccinations, and we encourage health care employers to maintain evidence-based policies regarding staff vaccination for COVID-19 and other communicable diseases for which vaccination is available and recommended. Health systems and health care employers may continue to require that workers stay up to date on COVID-19 vaccinations, consistent with other Federal, State, and local laws. Moreover, some States may require COVID-19 vaccination of

health care staff. Facilities must maintain compliance with applicable State and local laws pertaining to vaccination.

In this final rule, the substantive provisions of the staff vaccination IFC are withdrawn. Table 3 lists the regulatory locations from which staff vaccination regulations are addressed in this final rule by provider and supplier type.

TABLE 3. Withdrawn Regulations by Provider and Supplier Type

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

B. COVID-19 Vaccine “Educate and Offer” Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff

While the COVID-19 pandemic continues to evolve, effective vaccines and therapies have also been developed. Vaccination still remains as one of the most important methods to help reduce severity of COVID-19. However, some individuals may face additional barriers accessing COVID-19 vaccines. As previously discussed, many of the residents and clients of LTC facilities and ICF-IIDs are not able to independently travel offsite in order to receive a vaccine due to several factors including but not limited to disability, cognitive impairment, low health literacy, and/or functional reasons. Because some of these individuals may have a low health literacy, education on COVID-19 vaccines is particularly important. Vaccine education allows for residents, clients, and their caregivers to be informed participants in their care and

allows them to make the most appropriate decisions for themselves. Therefore, it is important that we maintain the educate and offer provisions for both LTC facilities and ICF-IIDs.

In this final rule, we are finalizing the infection control requirements at § 483.80(d) that LTC facilities must meet to participate in the Medicare and Medicaid programs. By doing so, LTC facilities must continue to educate and offer the COVID-19 vaccine to residents, resident representatives, and staff, as well as perform the appropriate documentation for these activities. All of the requirements of the educate and offer IFC are being finalized, except for the language referring to LTC facility staff refusing the COVID-19 vaccine originally set forth at § 483.80(d)(3)(v). We are finalizing this language as amended by the staff vaccination IFC.

We are also finalizing the COVID-19 facility staffing and health care services requirements at §§ 483.430(f) and 483.460 that ICFs-IID must meet to participate in the Medicare and Medicaid programs. By doing so, ICFs-IID must continue to educate clients, client representatives, and staff and offer the COVID-19 vaccine to clients and staff, as well as perform the appropriate documentation for these activities. All of the requirements of the educate and offer IFC are being finalized, except for the language referring to the ICFs-IID staff refusing the COVID-19 vaccine. We are finalizing this requirement as amended by the staff vaccination IFC.

C. COVID-19 Reporting Requirements for LTC Facilities

As previously discussed, CMS continues to evaluate and revise its policies pertaining to COVID-19 on an ongoing basis, and in light of the conclusion of the COVID-19 PHE, we are deleting the expired COVID-19 testing requirement for LTC facilities. We continue to emphasize the importance of practicing infection control measures in order to mitigate the spread of COVID-19 and other communicable respiratory diseases.

V. Severability

As described in further detail in the previous sections of this rule, this final rule relates to three separate IFCs: This final rule (1) withdraws requirements of the November 2021 IFC

regarding staff vaccination; (2) deletes expired requirements of the September 2020 IFC regarding COVID-19 testing in LTC Facilities, and (3) finalizes requirements of the May 2021 IFC requiring facilities to provide education about COVID-19 vaccines and to offer COVID-19 vaccines to residents, clients, and staff. As reflected by the fact that they these three categories of requirements appeared in three separate IFCs, the provisions of this final rule that relate to each of these three categories operate independently, and the agency intends that they be treated as severable. If any one of these categories of regulatory changes were stayed or invalidated by a reviewing court, the remaining categories would continue to effectuate the agency's intent to align its regulations with current public health conditions and would be independently administrable. Likewise, the agency intends that the provisions within each of these categories of regulatory changes be treated as severable. For example, were a court to stay or invalidate withdrawal of the staff vaccination requirement for one type of health care facility, the agency intends that the withdrawal of the requirement for other types of facilities would remain in effect. Accordingly, the agency considers each of the provisions adopted in this final rule to be severable; in the event of a stay or invalidation of any part of the rule, or of any provision as it applies to certain facilities or in certain factual circumstances, the agency's intent is to otherwise preserve the rule to the fullest possible extent.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 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 (OMB) 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 we 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 our 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.

In the staff vaccination IFC published November 5, 2021, the educate and offer IFC published May 13, 2021, and the LTC facility testing IFC published September 2, 2020, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). However, we did not receive any comments on these ICRs.

The following analysis covers the ICRs for the Staff Vaccination, Educate and Offer, and LTC testing requirements. As in the preamble above, we will first analyze the ICRs for the Staff Vaccination requirements first.

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 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 (OMB) for review and approval. 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 we 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 our 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.

This rule contains no new requirements and would sunset those promulgated by the staff vaccination IFC and the LTC testing IFC. The original estimates for the staff vaccination IFC

were 1,555,487 burden hours and \$136,088,221 for both the initial and subsequent years. The dollar estimates were based on hourly wage data from the Bureau of Labor Statistics for 2020. The original estimates for the LTC testing IFC were \$48,158,193 over the estimated course of the PHE. The dollar estimates were based on an estimated labor requirement of 2 minutes per test and hourly wage data from the Bureau of Labor Statistics for 2019. Based on the termination of the COVID-19 PHE and withdrawal of the vaccination and testing requirements, these estimates are reduced to zero in all succeeding months and years.⁶⁸

The original estimates for the educate and offer IFC were that first-year costs would be 1,277,874 burden hours and \$91,250,874. Subsequent year costs were estimated at 866,580 burden hours and \$55,177,044. The dollar estimates were based on hourly wage data from the Bureau of Labor Statistics for 2019. These estimates remain unchanged in this final rule, which makes no substantive changes to the regulations issued in that interim final rule.

VII. Regulatory Impact Analysis

A. Statement of Need

The COVID-19 pandemic precipitated the greatest health crisis in the U.S. since the 1918 Influenza pandemic. The population of older adults, and LTC facility residents in particular, were hard hit by the impacts of the pandemic. Among those infected, the death rate for older adults age 65 or higher was hundreds of times higher than for those in their 20s during 2020. Of the 1.1 million deaths through April 2023, only about 6,912 were for ages 18-29, compared to 850,000 for those age 65 or higher.⁶⁹ Moreover, of the approximately 1,130,662 Americans estimated to have died from COVID-19 through May 2, 2023, about 15 percent were estimated to have died during or after a LTC facility stay,⁷⁰ a percentage that has decreased substantially from earlier levels as vaccination rates increased for both residents and staff and as the

⁶⁸ See “Statement of Administration Policy”, Executive Office of the President, January 30, 2023, at <https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf>.

⁶⁹https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm.

⁷⁰<https://covid.cdc.gov/covid-data-tracker/#datatracker-home>

availability and use of effective medications to reduce the rates of hospitalization and death have rapidly grown.⁷¹ The proportion of the unvaccinated who have contracted the virus has also contributed to reducing the rate of future infections and their severity. As a result of all these factors, the Biden Administration allowed the public health emergency declaration under section 319 of the Public Health Service Act related to the COVID-19 pandemic to end on May 11, 2023.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 (Modernizing Regulatory Review) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity,

⁷¹ <https://www.kff.org/policy-watch/over-200000-residents-and-staff-in-long-term-care-facilities-have-died-from-covid-19/>.

competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for "significant regulatory actions" as defined in E.O. 12866 as amended by E.O. 14094. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) of E.O. 12866 as measured by the threshold of \$200 million or more in any 1 year, and hence also a rule qualifying under the definition in 5 U.S.C. 804(2) (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act).

Accordingly, we have prepared an RIA that, taken together with the collection of information (COI) analysis and other sections of this preamble, presents to the best of our ability the costs and benefits of the rulemaking. It is important to understand, as explained previously in this final rule, that this rule is terminating only one of the IFCs that were issued by CMS in response to the COVID-19 pandemic. The requirements for COVID-19 testing of LTC facility staff have already expired. The educate and offer IFC is being made permanent, substantively unchanged. Hence, the staff vaccination IFC is the only one substantively affected by this rule. Relative to a hypothetical future in which this and the educate and offer IFC continue unchanged, this rule reduces costs through the withdrawal of the omnibus staff vaccination requirements. It is economically significant under section 3(f)(1) of E.O. 12866 because the costs eliminated exceed \$200 million annually.

Due to the success of all three IFCs in encouraging both staff and patient vaccination in

health care settings, the evolution of SARS-CoV-2 toward variants whose adverse health impacts are on average less severe, and improved medications and reduced stresses on hospitals and other health care facilities, rates of severe illness and of death have both radically decreased since the staff vaccination IFC was issued. Of particular importance, the interactive effect of both staff and patient COVID-19 vaccination rates reaching or approaching 90 percent has helped each group protect the other. Vaccinating staff protects both staff and patients, as does vaccinating patients.⁷² In this regard, we emphasize that our current and planned use of data on both staff and patient vaccination rates will maintain consistent pressure on the health care providers and suppliers regulated by CMS to maintain and improve current success rates.

As displayed in detail in Tables 5 and 6 of the staff vaccination IFC, there are about 76,000 provider and supplier entities regulated by CMS, and these facilities have about 13 million staff during each year.⁷³ But large as these numbers are, they are dwarfed by the number of patients served. In total across all provider and supplier types, but excluding hospital outpatient and emergency caseloads, CMS-certified providers and suppliers serve over 100 million patients a year. Including patients served as hospital emergency cases or as outpatient cases, the total number of patients served is more than 300 million based on number of encounters, but likely to be much lower—about 250 million—based on number of different individuals. Thus, existing “educate and offer” requirements focus on both nursing home staff and patients.

The original staff vaccination IFC and this final rule present substantial difficulties in estimating both costs and benefits due to the high degree to which all current provider and supplier staff have already received information about the benefits and safety of COVID-19 vaccination and about the rare serious risks associated with vaccination. What is still uncertain is

⁷² We note that there is additional protection because many and very likely most of the remaining unvaccinated staff and patients previously have been infected by one or more COVID-19 variants, and therefore are less likely to experience severe COVID-19 in the near future. There are, however, no good data on the numbers or effects of these infections.

⁷³ See 86 FR 61603 and 61606, November 5, 2021.

how staff or patient compliance with recommended vaccinations may change further over time. Moreover, we do not know how many persons in each of these groups has become ill with COVID-19, and how many of these more than once, before coming into close contact. Nor do we know how these numbers are likely to change in the next few years, whether a new variant of the SARS-CoV-2 virus may emerge, or what new vaccines or treatment options may become common and with what effectiveness in preventing infection, hospitalization, or death. With all these unknown variables, we cannot predict with confidence future COVID-19 morbidity or mortality levels either with or without better vaccination compliance. However, we can estimate with some confidence a range of conditions in a hypothetical future in which the staff vaccination and educate-and-offer IFCs remain unchanged (assuming no new SARS-CoV-2 variant with higher or lower health effects becoming dominant, no new vaccine with higher protection against the existing variant, no major changes in vaccination practices, and no major changes in treatments), simply by using current data and projecting no major changes in these variables.⁷⁴

C. Anticipated Benefits and Costs

Relative to a hypothetical future in which the staff vaccination and educate-and-offer IFCs remain in their current form—which is one of multiple relevant analytic baselines—This rule imposes no new costs (other than the costs of reading and acting on this final rule). Instead, it reduces regulatory costs to health care providers and suppliers by withdrawing the requirements imposed by the staff vaccination IFC issued in November 2021. This final rule’s effect on numbers of lives lost of either health care staff or health care patients is limited by the scope of such outcomes in the analytic baseline (that is, the future trajectory in this rule’s absence). While the number of health care staff (whether called employees, workers, or staff) dying from COVID-19 infections was already decreasing when the staff vaccination IFC was

⁷⁴ For a list and discussion of past and present COVID variants, one useful and current source is Kathy Katella, “Omicron, Delta, Alpha and More: What To Know About the Coronavirus Variants,” February 3, 2023, at <https://www.yalemedicine.org/news/covid-19-variants-of-concern-omicron>.

issued, it has for the last year decreased to very low levels, often zero, for weeks at a time.⁷⁵ An unknown fraction of these deaths may have been vaccinated persons. Nor is there reason to believe that the relatively few recently recorded deaths from COVID-19 were due to workplace exposures, considering all the other locations at which workers might be exposed to the virus.⁷⁶ That said, we still do not know how much of this massive decrease in the mortality rate of infected populations was due to the policy effects of the IFC itself, but with the educate and offer rule now permanent, the fraction of staff and patients unvaccinated close to single digits (and never likely to have been much closer to zero given the various legally available exemptions), there is no plausible basis for estimating a resurgence of deaths among either group absent some new and more virulent COVID variant.

Perhaps the simplest way to understand these effects is to consider that in the roughly 18 months since the staff vaccination IFC rule was issued, much and perhaps most of the originally estimated costs (implementation) and benefits (lives saved) have already been realized. However, the many uncertainties that still affect projections into the future led us to restrict our cost horizons in the staff vaccination rule to one year and to eschew any mortality reduction estimate. In retrospect, it appears that while our cost estimates may have been reasonably robust, any estimate of lives saved would have likely been far too high. In particular, the reduced lethality of the Omicron variant of the virus and the available treatments for those ill from the virus were the largest life savers by far.⁷⁷

⁷⁵ The CDC Data Tracker for Covid, “Cases and Deaths among Healthcare Personnel,” estimates the total number of COVID-caused deaths among healthcare workers since the pandemic began is about 2,500, of which only about 200 have occurred in the last year (February to February). Data at https://covid.cdc.gov/covid-data-tracker/#health-care-personnel_healthcare-deaths.

⁷⁶ The Bureau of Labor Statistics estimates that there were about 5,000 annual fatal workplace injuries to workers in recent years. Accidents at work are only one of many causes of worker fatalities (for example, automobile injuries outside of the workplace, non-occupational illnesses of all kinds, and heart attacks while at work). In comparison, roughly 200 healthcare worker deaths occurred from COVID-19, much and perhaps most contracted outside the workplace. See CDC healthcare personnel data cited in preceding footnote, in comparison “to “National Census of Fatal Occupational Injuries in 2021” at <https://www.bls.gov/news.release/pdf/cfoi.pdf>.

⁷⁷ See W. Adjei et al., “Risk Among Patients Hospitalized Primarily for COVID-19 During the Omicron and Delta Variant Pandemic Periods,” *Morbidity and Mortality Weekly Report (MMWR)*, September 16, 2022; at <https://www.cdc.gov/mmwr/volumes/71/wr/mm7137a4.htm>. This report showed a two thirds reduction in mortality from the Delta period to the Omicron period.

Compliance Cost Reduction. In the staff vaccination IFC we estimated compliance and vaccination costs to be about \$1.382 billion in the first year and declined to estimate costs in succeeding years (see Table 7 in that rule).⁷⁸ This estimate attributed all implementation costs to that rule, with no offsetting assumption about spending that would otherwise have occurred. Thus, it attributed the vaccine costs for healthcare workers paid by the Federal Government to be a result of that rule. It omitted, however, potential increases in recruitment costs and a variety of potential business disruption costs for facilities that may have had difficulties hiring vaccinated workers. We estimated with these omissions because we had no reliable way to estimate how much of these costs might be due to independent employer decisions, to other Federal standards, to State and local mandates, or to individual personal choices. In retrospect, this was a reasonable estimate because we still have no basis for “correcting” the original assumption. Moreover, if such costs were not paid by the government directly, both public and private insurance would have covered most of these costs in future years (and likely will cover them for voluntary vaccinations). Regardless, a substantial fraction of those costs would have been expected to recur each year, if for no other reason than turnover among health care staff. However, since the first year included primary series vaccination of all existing staff, succeeding years would have been lower in cost because the number of required vaccinations would largely be incurred only for new workers, and only some of these would not have been previously vaccinated through other sources. Furthermore, only in the first year would one-time costs (such as reading the rule and creating policies and procedures to implement the rule) have been incurred. We therefore now estimate that to maintain that rule only about one-half of the first-year estimate would have been needed to comply in future years.

For purposes of estimating benefits from eliminating the implementation costs of the staff vaccination IFC, we therefore estimate that the second- and third-year costs of the November 2021 staff vaccination IFC (if continued unchanged) would have been \$691 million (0.5 *

⁷⁸ 86 FR 61609, November 5, 2021.

1,382). Had we estimated fourth and fifth (or later) years on the same basis, costs near those levels would presumably have continued. Subtracting an additional \$4 million for the one-time costs of reading and acting on this final rule, the next year of benefits of this rule in costs reduced from the estimated annual level in the November 2021 interim final rule would be \$687 million, followed by future years at \$691 million (until something unforeseen changed).

We note that these cost (now benefit) estimates apply only to the mandatory nature of the rule addressing staff vaccination. As discussed in the next section of this RIA, we believe it very likely that many and probably most health care providers and suppliers will continue to require or strongly urge staff vaccination and that staff vaccination rates will rise over time as new generations of workers who received past vaccinations will be hired. The precise evolution of these trends will depend on the many uncertainties already discussed, and the result may be higher or lower changes in costs than those anticipated at the time the interim final rule was issued (and thus higher or lower savings than what is estimated now). Given experiences to date, however, we believe that the future benefits (lives saved) of continuing the staff vaccination requirements would have been low at the time of our estimate and very low if made in the light of recent experience. We continue to believe, however, that reliable forecasts of morbidity and mortality over any time horizon more than a few months cannot yet be made.

We again note that the LTC testing requirements expired before publication of this final rule. This rule was not a factor in that expiration and we accordingly do not address the estimated costs and benefits of that change.

The preceding discussion applies to the staff vaccination IFC. The May 2021 educate-and-offer IFC is not being changed, and the original compliance cost estimates in that rule included future year projections.⁷⁹ These projections showed lower estimates for future years than upfront, in large part because the need for development of policies, procedures, and educational materials would be greatly reduced over time. Those future year estimates were then

⁷⁹ See Table 6 in that rule, at 86 FR 26330, May 13, 2021.

and remain uncertain for most of the same reasons already discussed with respect to the staff vaccination IFC. We have no basis for changing the overall estimated total future year compliance costs from the estimates made at that time.

Changes in Worker Lives Saved or Lost. Ending the staff vaccination IFC could arguably reduce vaccination levels among health care staff. However, the direct effect of this regulatory change is not necessarily to reduce the level of vaccination among health care staff, but to eliminate the government requirements for facilities to track and manage vaccination. We believe it possible, in fact, that provider and staff self-interest will persuade current or future vaccine-hesitant or newly hired staff, or both, about the safety and effectiveness of current vaccines. This opportunity is particularly large for booster shots, since only about 22 percent of nursing home staff, and presumably a similar percentage for other provider types, have even obtained the first booster.⁸⁰ Another positive factor may be the influence of educational institutions that train future care personnel in persuading or requiring their students to accept vaccination while in school, before taking jobs in the health care sector. Finally, the willingness of health care employers to simply require vaccination (in the vast majority of States where this is allowed) is a significant and potentially highly positive factor.⁸¹

The most influential variables in predicting future lives saved or lost are likely to be the new SARS-CoV-2 variants that make the initial vaccines less effective in preventing COVID-19. However, the new variants have generally been less harmful for most of those who have received vaccinations. Additional doses of COVID-19 vaccines provide protection against COVID-19 but immunity declines over time. These are all variables that interact, and their understanding by healthcare personnel depends substantially on the effectiveness of education and offering efforts by applicable health care providers. Further, many Americans have been infected with COVID-

⁸⁰ <https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html>.

⁸¹ The CDC has collected data on State laws either prohibiting (often with exceptions) or mandating (often with exceptions) employer-or local government-mandated COVID-19 vaccination or testing. Few States and none of the larger States have created by law prohibitions that would apply to healthcare or long-term care employers. The statutes mainly address compulsion by lower levels of government, such as cities or counties.

19 and may have developed some level of infection-induced immunity, which provides some protections as well. Since the educate and offer requirements are being retained and will be reinforced by new quality measures, as well as the extent to which future patients respond to high and low scores on these measures, we believe that any overall change in morbidity and mortality from the repeal of the provisions of the staff vaccination IFC would be smaller than what would result from repeal occurring (hypothetically) without the continuation of education-and-offering requirements.

Quite apart from changes in vaccination levels from those either originally estimated or currently in place, the morbidity and mortality of COVID-19 have changed substantially since 2021. In particular, the currently dominant strain of the virus results in much lower levels of severity, thereby lowering both hospitalizations and death. Current treatment options reduce severity levels even further.⁸² Assuming no further change in vaccination levels, treatment options, or in COVID-caused severity of illness, currently available information can be used to create rough estimates of conditions in a hypothetical future in which the IFCs remain in their current form. Most importantly, COVID-caused deaths have fallen substantially since the levels measured in or before 2021. According to CDC estimates, the number of deaths caused by COVID-19 among healthcare workers has fallen from dozens per week to close to zero.⁸³ Specifically, in the last year (beginning of February 2022 through end of January 2023) the number of known healthcare worker deaths per week has ranged from 0 to 4 (CDC says “less than 5”) and therefore has averaged about 2 per week, or a rate of approximately 100 per year.⁸⁴ Since a fraction of these deaths presumably were of those infected outside the workplace, or among those already vaccinated (given the percentage of adults in the United States who have received a COVID-19 vaccine), or both, the termination of the staff vaccination IFC is estimated

⁸² <https://www.idsociety.org/covid-19-real-time-learning-network/emerging-variants/emerging-covid-19-variants/>.

⁸³ https://covid.cdc.gov/covid-data-tracker/#health-care-personnel_healthcare-deaths.

⁸⁴ CDC’s website acknowledges that these data have gaps and other imperfections, but the crucial point seems clear. From the full set of these sources, however imperfect, the number of cases is down substantially, and the number and rates of deaths have decreased even further compared to the first 2 years of the pandemic.

to have minimal effects.

As discussed elsewhere in the preamble, we intend to establish measures on COVID-19 infection prevention to our quality improvement measures for most types of health care facilities. This is a far more flexible system than detailed regulations and will allow tailoring of actions and accomplishments down to the facility level, responding in real-time to any changes in SARS-CoV-2 variants, drug treatments, and other factors that improve either staff or patient health outcomes, including innovations that protect either group through the other, or both at once. For example, improved ventilation systems have been demonstrated to reduce airborne infections for any exposed persons, including staff, patients, and visitors.⁸⁵

Therefore, and subject to all the uncertainties and unknowns discussed earlier in this analysis that might lead to higher or lower numbers, there is no known reason to expect that repeal of the staff vaccination IFC will lead to a substantial or measurable increase or decrease in health care worker deaths, despite the many uncertainties and unknowns involved.

Changes in Patient Lives Saved or Lost. Most of the same factors that apply to staff apply with equal force to patients. There are, however, several key differences. First, CMS has long required that LTC facilities and IICFs-IID both encourage and arrange vaccination of patients with the annual influenza vaccine and the pneumococcal vaccine. These requirements now include COVID-19 vaccination following the educate and offer IFC that we are now making permanent and thus no longer contingent on the scope or magnitude of COVID-19 infections. These facilities are the most important locations for patient education, both to protect other patients and to protect staff.

Second, the location where a patient is treated or dies may have little or no relevance to where they became infected.⁸⁶ This is true, of course, for workers as well. Many and perhaps

⁸⁵ See CDC, "Ventilation in Buildings," June 2, 2021 version, at <https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html>, and Ehsan Mousavi et al, "COVID-19 Outbreak and Hospital Air Quality: A Systematic Review of Evidence on Air Filtration and Recirculation," American Chemical Society Public Health Emergency Collection, August 26, 2020, at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7489049/>.

⁸⁶ Of course, this would not apply equally in all health care settings. Quick outpatient visits and long-term care residence would not show the same location of infection patterns.

most worker infections undoubtedly come from contacts with infected individuals in external places such as sporting events, grocery stores, clubs, restaurants, and bars. But for health care these patterns are even more complex. The person who tests positive upon admission to a hospital most likely reached the hospital after contracting the disease in another setting.

It is also true that there are many more patient lives than staff lives at issue. While health care staff deaths from COVID-19 appear to have reached single digits on a weekly basis the total national weekly number of COVID-19 deaths has been about 3,000 on average for over 6 months.⁸⁷ Assuming no change, the number of COVID-19 deaths will be about 160,000 in 2023, about 5 percent of the national total of about 3.5 million annual deaths from all causes (and half the COVID-19 number in 2020).

D. Other Effects

There are no substantial budgetary effects of this final rule. Current payments for vaccine are federally financed, and not driven by whether there is a PHE for COVID-19 declared under section 319 of the Public Health Service Act. When the current budget for the vaccines runs out, private and public health insurance will in most cases assume the costs of vaccination, depending on future coverage decisions by these insurance programs. Likewise, there is little or no reason to expect that the expiration of the LTC facility testing IFC will have a consequential effect.

1. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Under the RFA, “small entities” include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, we estimate that most health care facilities are small entities as that term is used in the RFA because they are either nonprofit organizations or meet the SBA definition of a small

⁸⁷ See the Data Table for Weekly Death Trends in CDC’s COVID Data Tracker. Only a handful of weeks have reached or exceeded 3,500 deaths since May 2022 as shown in this table, at https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.

business (for most types of health care providers, having revenues of less than \$8.0 million to \$41.5 million in any 1 year). HHS uses an increase in costs or decrease in revenues to a provider of more than 3 to 5 percent as its measure of “significant economic impact.” The HHS standard for “substantial number” is 5 percent or more of those that will be significantly impacted, but never fewer than 20.

This final rule was not preceded by a general notice of proposed rulemaking and the RFA requirement for a final regulatory flexibility analysis does not apply to final rules not preceded by a proposed rule. Regardless, this rule would not trigger the RFA requirement. As estimated previously, the total savings from this rule for future years are about \$691 million annually. Spread over 13 million full-time equivalent health care employees, this is about \$53 per employee. Assuming a fully loaded average wage and support cost per employee of \$90,000,⁸⁸ the annual savings do not approach the 3 percent threshold. Furthermore, the Department interprets the RFA’s definition of “significant economic impact” as applying only to newly imposed adverse effects, not to cost reductions or other savings. For these reasons, the Department has determined that this final rule will not have a significant adverse economic impact on a substantial number of small entities and that a final Regulatory Flexibility Analysis is not required. Regardless, the content of this RIA and the main preamble, taken together, would meet the requirements for a Final Regulatory Flexibility Analysis.

2. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare an RIA if a proposed or final rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of this requirement, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule is exempt because that provision of law only applies to those final rules for which a proposed rule was published.

⁸⁸ This is the rounded weighted average annual cost of healthcare employees as estimated in the Totals line of Table 4 of the mandated vaccination interim final rule issued in November of 2021, *op cit*.

Because this rule has only the small and positive impact per employee calculated for RFA purposes, the Department has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

3. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will impose spending costs on State, local, or Tribal governments, or by the private sector, require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately \$175 million. This final rule was not preceded by a notice of proposed rulemaking, and therefore the requirements of UMRA do not apply. Regardless, this rule contains no State, local, or Tribal governmental mandates, nor any mandates on private sector entities that were not previously included in prior rules. Moreover, it saves rather than increases costs. The analysis in this RIA and the preamble as a whole would, however, meet the requirements of UMRA.

4. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct effects on State and local governments, preempts State law, or otherwise has federalism implications. While the staff vaccination IFC did preempt some State laws, those effects did not involve “substantial direct costs” and this final rule repeals those preemptions. Accordingly, the requirements of E.O. 13132 do not apply to this final rule.

E. Alternatives Considered

While we considered retaining the requirements established in the staff vaccination IFC, we believe that it has largely served its emergency purpose of protecting the health and safety of patients. As previously discussed in this RIA, about 86 percent of nursing home staff have

completed the original primary vaccination series, helping reduce risk to patients.⁸⁹ Moreover, many and likely most of the remaining staff have previously been infected by COVID-19 and benefit from some protective immunity.⁹⁰ We also note that the subject addressed by this rule is whether or not to extend and/or modify the staff vaccination IFC, not the array of actions pursued with the many tools and venues which the Federal Government uses, such as vaccine research.

In the population as a whole, as of March 29, 2023, COVID-19 death rates have decreased to about 323 a week, still far too high but a decreasing fraction of the 3.5 million annual and 66,000 weekly deaths from all causes in the United States.^{91,92} With regard to health care staff, the progress has been even more rapid, with staff deaths attributed to COVID-19 trending downward since late 2021 and remaining relatively low over the past year.⁹³ Given the many uncertainties as to future events, and with the option of new emergency regulations available under appropriate circumstances if progress is halted or reversed, a rule tailored to future events could always be created should the data justify such an action.

While not otherwise addressed in this RIA, we did consider whether it might be appropriate to not finalize the educate and offer IFC but as discussed in this rule recognize the importance of ongoing access to vaccination for individuals residing in congregate care settings. Additionally, we also considered whether we could or should extend the LTC facility testing requirements that expired with the PHE, and determined that there was no need in the face of current standards of care that call for testing when clinically indicated.

F. Accounting Statement and Table

⁸⁹ https://www.cdc.gov/nhsn/covid19/lte-vaccination-dashboard.html#anchor_1638315381394.

⁹⁰ Reinfection of previously vaccinated persons or of previously infected persons would make them a temporary risk, but the frequency of this problem appears to be quite low. It remains, however, yet another future unknown.

⁹¹ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>.

⁹² Farida Ahmad et al, "Provisional Mortality Data – United States, 2021," at <https://pubmed.ncbi.nlm.nih.gov/35482572/>.

⁹³ <https://covid.cdc.gov/covid-data-tracker/#health-care-personnel>, Of 98,807,297 case reports received by CDC, 13,207,516 (13.37 percent) have known healthcare personnel (HCP) status. Completion of HCP status varied in case reporting over time and is noted in the figure and table below. For the 1,145,831 cases of COVID-19 among HCP, death status is available for 636,341 (55.54 percent).

The Accounting Table (Table 4) summarizes the quantified impact of this rule. It covers only 3 years because there will likely be new developments regarding treatments and vaccinations and their effects in future years and we have no way of knowing which will most likely occur. A longer period would be even more speculative than the current estimates.

As explained in various places within this RIA and throughout this final rule, there are major uncertainties as to the effects of current or possible future variants of SARS-CoV-2 on future infection rates, medical treatments and costs, and prevention of major illness or mortality. Even the duration of vaccine effectiveness in preventing COVID-19, reducing disease severity, and risk of death, by those vaccinated are not currently known with precision or certainty. These uncertainties also impinge on benefits estimates. For those reasons we have not quantified into annual totals the effects on mortality risk of this rulemaking or of other actions (including the retention of the educate and offer IFC for LTC facilities and ICFs-IID, which would have a life-extending effect relative to an analytic baseline in which the future is characterized by a hypothetical absence of that IFC⁹⁴) and have used only a 3-year projection for the cost savings estimates in our Accounting Statement. We also show a range (plus or minus 25 percent) for the upper and lower bounds of potential cost savings to emphasize the uncertainty as to several major variables, including changes in voluntary vaccination levels, longer-term effects, and others previously discussed.

⁹⁴ Relative to this without-IFC baseline, the finalized requirements would also impose cost, as estimated at the time of the IFC's issuance.

TABLE 4: Accounting Statement—Classification of Estimated Costs and Savings Relative to an Analytic Baseline in which the Staff Vaccination and Educate-and-Offer IFCs Are Retained Into the Future
(\$ millions)

Category	Primary Estimate	Lower Bound	Upper Bound	Units		
				Year Dollars	Discount Rate	Period Covered
Benefits Annualized and Monetized (\$millions/year)	\$690	\$518	\$862	2022	7%	2023-2025
	\$690	\$518	\$862	2022	3%	2023-2025
Benefits Notes: The benefits of this rule are the estimated reductions in costs from ending requirements for mandatory staff vaccinations.						
Costs (not annualized or monetized)				2022	7%	2023-2025
				2022	3%	2023-2025
Costs Notes: The estimated effects of this rule on staff and patient lives saved or lost from COVID-19 infections are not estimated.						
Transfers	None					

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 11, 2023.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Administrative practice and procedure, Grant programs-health, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 486

Administrative practice and procedure, Grant programs—health, Health facilities, Home infusion therapy, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural and urban areas.

42 CFR Part 494

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV to remove expired language and finalize certain provisions issued in the interim final rule published at 85 FR 54820 (September 2, 2020); to finalize certain provisions issued in the interim final rule published at 86 FR 26306 (May 13, 2021); and to withdraw the regulations issued in the interim final rule published at 86 FR 61555 (November 5, 2021) as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 416.51 [Amended]

2. Section 416.51 is amended by removing paragraph (c).

PART 418—HOSPICE CARE

3. The authority citation for part 418 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 418.60 [Amended]

4. Section 418.60 is amended by removing paragraph (d).

**PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO
SPECIFIC SERVICES**

5. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

§ 441.151 [Amended]

6. Section 441.151 is amended by removing paragraph (c).

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

7. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f).

§ 460.74 [Amended]

8. Section 460.74 is amended by removing paragraph (d).

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

9. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

§ 482.42 [Amended]

10. Section 482.42 is amended by removing paragraph (g).

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

11. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1395i, 1395hh and 1396r.

§ 483.80 [Amended]

12. Section 483.80 is amended by removing paragraphs (h) and (i).

§ 483.430 [Amended]

13. Section 483.430 is amended by removing paragraph (f).

PART 484—HOME HEALTH SERVICES

14. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 484.70 [Amended]

15. Section 484.70 is amended by removing paragraph (d).

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

16. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

§ 485.58 [Amended]

17. Section 485.58 is amended in paragraph (d)(4) by removing the last sentence.

§ 485.70 [Amended]

18. Section 485.70 is amended by removing paragraph (n).

§ 485.640 [Amended]

19. Section 485.640 is amended by removing and reserving paragraph (f).

§ 485.725 [Amended]

20. Section 485.725 is amended by removing paragraph (f).

§ 485.904 [Amended]

21. Section 485.904 is amended by removing paragraph (c).

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES

FURNISHED BY SUPPLIERS

22. The authority citation for part 486 continues to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b-8, and 1395hh.

§ 486.525 [Amended]

23. Section 486.525 is amended by removing paragraph (c).

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

24. The authority citation for part 491 continues to read as follows:

Authority: 42 U.S.C. 263a and 1302.

§ 491.8 [Amended]

25. Section 491.8 is amended by removing paragraph (d).

**PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE
FACILITIES**

27. The authority citation for part 494 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 494.30 [Amended]

28. Section 494.30 is amended by removing paragraph (b) and redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2023-11449 Filed: 5/31/2023 4:15 pm; Publication Date: 6/5/2023]