



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

[CMS-3414-IFC]

RIN 0938-AU57

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

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) revises the infection control requirements that long-term care (LTC) facilities (Medicaid nursing facilities and Medicare skilled nursing facilities, also collectively known as “nursing homes”) and intermediate care facilities for individuals with intellectual disabilities (ICFs-IID) must meet to participate in the Medicare and Medicaid programs. This IFC aims to reduce the spread of SARS-CoV-2 infections, the virus that causes COVID-19, by requiring education about COVID-19 vaccines for LTC facility residents, ICF-IID clients, and staff serving both populations, and by requiring that such vaccines, when available, be offered to all residents, clients, and staff. It also requires LTC facilities to report COVID-19 vaccination status of residents and staff to the Centers for Disease Control and Prevention (CDC). These requirements are necessary to help protect the health and safety of ICF-IID clients and LTC facility residents. In addition, the rule solicits public comments on the potential application of these or other requirements to other congregate living settings over which CMS has regulatory or other oversight authority.

DATES: These regulations are effective on [Insert date 10 days after filing for public inspection in the **Federal Register**].

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-3414-IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-3414-IFC,

P.O. Box 8010,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-3414-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Diane Corning, (410) 786-8486, Lauren Oviatt, (410) 786-4683, Kim Roche, (410) 786-3524, or Kristin Shifflett, (410) 786-4133, for all rule related issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Currently, the United States (U.S.) is responding to a public health emergency of respiratory disease caused by a novel coronavirus that has now been detected in more than 190 countries internationally, all 50 States, the District of Columbia, and all U.S. territories. The virus has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2), and the disease it causes has been named “coronavirus disease 2019” (COVID-19). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak 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 to aid the nation's health care community in responding to COVID-19 (hereafter referred to as the PHE for COVID-19). On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, the President of the United States declared the COVID-19 pandemic a national emergency. The January 31, 2020 determination that a PHE for COVID-19 exists and has existed since January 27, 2020, lasted for 90 days, and was renewed on April 21, 2020; July 23, 2020; October 2, 2020; and January 7, 2021. Pursuant to section 319 of the PHS Act, the determination that a PHE continues to exist may be renewed at the end of each 90-day period.¹ Data from the Centers for Disease Control and Prevention (CDC) and other sources have determined that some people are at higher risk of severe illness from COVID-19.²

Individuals residing in congregate settings, regardless of health or medical conditions, are at greater risk of acquiring infections, and many residents and clients of long-term care (LTC) facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) face higher risk of severe illness due to age, disability, or underlying health conditions. Nursing home residents are less than 1 percent of the American population, but have historically accounted for over one-third of all COVID-19 deaths.³

A. COVID-19 in Congregate Living Settings

Since there is no single official definition of congregate living settings, also referred to as residential habilitation settings, for purposes of this discussion we describe them as shared residences of any size that provide services to clients and residents. People living and working in these living situations may have challenges with social distancing and other mitigation

¹ <https://www.phe.gov/emergency/events/COVID19/Pages/2019-Public-Health-and-Medical-Emergency-Declarations-and-Waivers.aspx>

² Centers for Disease Control and Prevention. (2020). People at Increased Risk. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>

³ See The Long-Term Care COVID Tracker at <https://covidtracking.com/nursing-homes-long-term-care-facilities>, and the KFF State COVID-19 Data and Policy Actions at <https://www.kff.org/coronavirus-covid-19/issue-brief/state-covid-19-data-and-policy-actions/#longtermcare>. These data may understate the problem because some states do not count as nursing home deaths persons infected in nursing homes but transferred to hospitals and recorded as hospital deaths.

measures, like mask use and handwashing, that help to prevent the spread of SARS-CoV-2. Residents, clients, and staff typically may gather together closely for social, leisure, and recreational activities, shared dining, and/or use of shared equipment, such as kitchen appliances, laundry facilities, vestibules, stairwells, and elevators. Residents in some congregate living facilities may also receive care from day habilitation facilities such as adult day health centers. Some congregate living residents require close assistance and support from facility staff, which further reduces their ability to maintain physical distance. On March 2, 2021, CDC issued *Interim Considerations for Phased Implementation of COVID-19 Vaccination and Sub-Prioritization Among Recommended Populations*, which notes that increased rates of transmission have been observed in these settings, and that jurisdictions may choose to prioritize vaccination of persons living in congregate settings based on local, state, tribal, or territorial epidemiology. CDC further notes that congregate living facilities may choose to vaccinate residents and clients at the same time as staff, because of shared increased risk of disease.⁴

This rule establishes requirements for LTC facilities and ICFs-IID; however, we recognize that individuals in all congregate living settings may have had similar experiences and outcomes during the PHE as individuals living or staying in institutional settings. We acknowledge that many congregate living facilities may not fall into any single category or may be classified differently depending on the state in which they are located. We further note that some other congregate living settings, such as dormitories, prisons, and shelters for people experiencing homelessness, have also faced higher risks of disease transmission, and these settings are not within our scope of authority. CMS is seeking public comment on the feasibility of implementing vaccination policies for other Medicare/Medicaid participating shared residences in which one or more people reside such as but not limited to the following: psychiatric residential treatment facilities (PRTFs), psychiatric hospitals, forensic hospitals, adult

4 <https://www.cdc.gov/vaccines/covid-19/phased-implementation.html#congregate-living-settings>

foster care homes (AFC homes), group homes, assisted living facilities (ALFs), supervised apartments, and inpatient hospice facilities.

We considered extending the requirements included in this rule to other congregate living settings for which we have regulatory authority, including inpatient psychiatric hospitals (which are subject to the majority of Hospital Conditions of Participation, including § 482.42, “Infection Control”) and PRTFs, but have not included such requirements in this interim final rule because we believe it would not be feasible at this time. Individuals in psychiatric hospitals, for example, may only be in-patients for short periods, making appropriate provision of a two-dose vaccine series challenging, although a one dose vaccine product is also now authorized. Because we are not able to guarantee sufficient availability of single dose COVID-19 vaccines at this time, or in the near future, to meet the potential demands of facilities with relatively short stays, we are focusing on facilities that have longer term relationships with patients and are thus also able to administer all doses of and track multi-dose vaccines. PRTFs only serve children and youth under the age of 21 years, and there is not yet a COVID-19 vaccine authorized or licensed for people younger than the age of 16 years in the United States. We are seeking public comment on the feasibility of adding appropriate COVID-19 vaccination requirements for residents, clients, and staff of all congregate living facilities where CMS has regulatory authority and pays for some portion of the care and services provided. Specifically, we are interested in comments on potential barriers facilities may face in meeting the requirements, such as staffing issues or characteristics of the resident or client population, and potential unintended consequences. We welcome suggestions on how the regulations should be revised to ensure that congregate living within our regulatory authority are able to reduce the spread of SARS-CoV-2 infections.

While congregate living settings are also often part of a state’s and home and community-based services (HCBS) infrastructure. HCBS is an umbrella term for long term services and supports that are provided to people in their own homes or communities rather than institutions or other isolated settings. These programs serve a diverse population, including

people with intellectual or developmental disabilities, physical disabilities, mental illness, and HIV/AIDS. Shared living arrangements within, and the sharing of staff across these and other settings can lead to increased risk of COVID-19 outbreaks. In addition, individuals living in these settings often have multiple chronic conditions that can increase the risk of severe disease and complicate treatment of, and recovery from, COVID-19. This makes the vaccination of clients and staff in these congregate living settings a critical component of a jurisdiction's vaccine implementation plan.

In an effort to facilitate a comprehensive vaccine administration strategy, we encourage providers who manage Medicare and/or Medicaid participating congregate living settings (such as psychiatric hospitals or PRTFs) or settings in which Medicaid-funded HCBSs are provided (ALFs, group homes, shared living/host home settings, supported living settings, and others) to voluntarily engage in the provision of the culturally and linguistically appropriate and accessible education and vaccine-offering activities described in this IFC. Vaccine availability may vary based on location, and vaccination and medical staff authorized to administer the vaccination may not be readily available onsite at many congregate living or residential care settings. Therefore, facilities should consult state Medicaid agencies and state and local health departments to understand the range of options for how vaccine provision can be made available to residents, clients, and staff. In addition, we encourage state Medicaid agencies, in partnership with public health agencies, to collaborate with congregate living settings to ensure their involvement in vaccine distribution strategies, and to facilitate vaccination of beneficiaries and staff as efficiently as possible. Lastly, we request public comment on challenges congregate living settings might encounter in complying with these IFC provisions, including in reporting vaccine information to CDC's National Healthcare Safety Network (NHSN).

We acknowledge the diversity and complexity of the needs of congregate living facilities. We understand that factors such as coordination of care with day habilitation sites, adult day health providers, hospice providers, and other entities, and also high rates of staff turnover may

impede the implementation of a COVID-19 vaccination program. To enhance our future efforts to support reasonable and effective COVID-19 vaccination programs in congregate living facilities, we seek public comment on a number of issues, including the following:

- Are there state or local vaccine policies, for COVID-19 vaccines or otherwise, already in place for congregate living facilities and related agencies, such as adult day health programs, either in the licensing or certification requirements or elsewhere? How have they been helpful to your facility or program?

- Does your program or facility have vaccine policies? How are they structured and what challenges have you faced with regard to implementation? Do policies include residents, clients and staff?

- If a vaccine policy applied to both shared living and day programs for adult day health or day habilitation, for example, who or what entity should have the responsibility for ensuring that all residents and staff have access to COVID-19 vaccination? Is there existing or capacity for case management for individuals engaging with both residential care and programs that occur outside the residential setting?

- What barriers exist to the implementation of a COVID-19 vaccination policy for residents and staff of congregate living facilities?

- How can equitable access to COVID-19 vaccine be ensured for residents and clients of congregate living facilities and related agencies?

- Are congregate living facilities currently facing challenges in tracking staff vaccination status? If so, explain.

- Has your State or county included residential and adult day health or day habilitation staff on the vaccine-eligible list as health care providers? What other impediments do staff face in getting access to vaccines?

Where such data are available, we are requesting respondents include data indicating:

- The rate of admission to congregate living facilities.

- The average length of stay for residents of congregate living facilities.
- The variety and prevalence of comorbidities in individuals served that may increase their risk of severe illness from COVID-19.
- The rate of employee sharing between congregate living facilities and the rate of employee turnover.

We acknowledge the lengths that congregate living and HCBS providers have gone to keep their residents, clients, and staff as safe as possible during the COVID-19 PHE, and request their input on ways that CMS and HHS can further support safety and reduce the risk of infection moving forward. This interim final rule with comment is one step in the broad effort to support those individuals at higher risk, in part because of living or working arrangements. Comments from congregate living providers, advocacy groups, professional organizations, HCBS providers (including day habilitation and adult day health providers), residents, clients, staff, family members, paid and unpaid caregivers, and other stakeholders will help inform future CMS actions.

B. ICFs-IID and COVID-19

ICFs-IID, residential facilities that provide services for people with disabilities, vary in size. In such settings, several factors may facilitate the introduction and spread of SARS-CoV-2, the virus that causes COVID-19. Staff working in these facilities often work across facility types (that is, nursing home, group home, different congregate settings within the employer's purview), and for different providers, which may contribute to disease transmission. Other factors impacting virus transmission in these settings might include: clients who are employed outside the congregate living setting; clients who require close contact with staff or direct service providers; clients who have difficulty understanding information or practicing preventive measures; and clients in close contact with each other in shared living or working spaces. ICF-IID clients with certain underlying medical or psychiatric conditions may be at increased

risk of serious illness from COVID-19.⁵

There are currently 5,768 Medicare- and/or Medicaid-certified ICFs-IID, and all 50 States have at least one ICF-IID. As of April 2021, 4,661 of the 5,770 are small (1 to 8 beds) in size, but there are 1,107 that are larger (14 or more beds) facilities. These facilities serve over 64,812 individuals with intellectual disabilities and other related conditions. ICFs-IIDs were originally conceived as large institutions, but caregivers and policymakers quickly recognized the potential benefits of greater community integration, spawning the growth in the early 1980s of community ICFs-IID with between four and 15 beds.⁶ The number of individuals residing in large public ICFs-IID has decreased steadily over time (from 55,000 total residents in 1997 to approximately 16,000 as of April 2021). Many states have either closed a significant number of these facilities completely or downsized them through “rebalancing” efforts,⁷ and the impetus of the Supreme Court’s *Olmstead* decision.⁸ Many ICF-IID clients have multiple chronic conditions and psychiatric conditions in addition to their intellectual disability, which can impact a client’s understanding or acceptance of the need for vaccination. All must financially qualify for Medicaid assistance. While national data about ICF-IID clients is limited, we take an example from Florida, almost one quarter (23 percent) require 24-hour nursing services and a medical care plan in addition to their services plans.⁹ Data from a single state is not nationally representative and thus we are unable to generalize, but it is illustrative and consistent with other states’ trends. These co-occurring conditions may increase the risks of infectious diseases for clients of ICFs-IID above the risk levels experienced by the general population. Clients and residents often live in close quarters. Some may not understand the dangers of the virus, or be able to independently comply with mitigation measures. Those who need help with activities of daily living cannot maintain their distance from staff and caregivers. During the PHE, some

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>

⁶ <https://aspe.hhs.gov/system/files/pdf/76956/MFIS.pdf>

⁷ <https://www.medicaid.gov/sites/default/files/2019-12/mfp-rtc.pdf>

⁸ <https://www.ada.gov/olmstead/S>

⁹ <http://www.floridaarf.org/assets/Files/ICF-IID%20Info%20Center/ICFHandoutonWebsite2-14.pdf>

facilities have struggled to retain staff and, as noted above, some staff working in these facilities may also have more than one job that puts them at higher risk.¹⁰ Currently, the Conditions of Participation: “Health Care Services” at § 483.460(a)(3), require ICFs-IID to provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following: evaluation of vision and hearing; immunizations; routine screening laboratory examinations as determined necessary by the physician, special studies when needed; and tuberculosis control, appropriate to the facility’s population. While the existing requirements should ensure that ICFs-IID provide clients with a COVID-19 vaccine, we note that it does not address vaccine education. Further, we believe that the unprecedented risks associated with the COVID-19 PHE warrant direct attention. ICFs-IID have not historically been required to participate in national reporting programs to the extent that other health care facilities have. Despite the limited data available regarding COVID-19 cases or outbreak in ICFs-IID, we recognize the unique concerns for these facilities and their clients and staff. We note that CDC has established COVID-19 infection, prevention, and control guidance specific to group homes for individuals with disabilities, as noted earlier, recently released an updated guidance on vaccination and sub-prioritization that discusses this group.¹¹

CMS and other Federal agencies took many actions and exercised regulatory flexibilities to help health care providers contain the spread of SARS-CoV-2. When the President declares a national emergency under the National Emergencies Act or an emergency or disaster under the Stafford Act, CMS is empowered to take proactive steps by waiving certain CMS regulations, as authorized under section 1135 of the Social Security Act (“1135 waivers”). CMS may also waive requirements set out under section 1812(f) of the Social Security Act (the Act) applicable to skilled nursing facilities (SNFs) under Medicare (“1812(f) waivers”). The 1135 waivers and 1812(f) waivers allowed us to rapidly expand efforts to help control the spread of SARS-CoV-2.

¹⁰ <https://www.medicaid.gov/medicaid/long-term-services-supports/workforce-initiative/index.html>

¹¹ <https://www.cdc.gov/coronavirus/2019-ncov/community/group-homes.html>

Currently, CMS has waived the following regulations for ICF-IIDs, with a retroactive effective date of March 1, 2020, and continuing through the end of the public health emergency declaration and any extensions, unless they are terminated earlier. CMS has waived the requirements at § 483.430(c)(4), which requires the facility to provide sufficient Direct Support Staff (DSS) so that Direct Care Staff (DCS) are not required to perform support services that interfere with direct client care. We also waived the requirements at § 483.420(a)(11) which requires clients have the opportunity to participate in social, religious, and community group activities. Finally, we also waived, in part, the requirements at § 483.430(e)(1) related to routine staff training programs unrelated to the public health emergency. CMS has not waived § 483.430(e)(2) through (4), which requires focusing on the clients' developmental, behavioral, and health needs and being able to demonstrate skills related to interventions for challenging behaviors and implementing individual plans.

CMS recognizes that during the public health emergency "active treatment" may need to be modified. The requirements at § 483.440(a)(1) require that each client receive a continuous active treatment program, which includes consistent implementation of a program of specialized and generic training, treatment, health services and related services. CMS is currently waiving those components of beneficiaries' active treatment programs and training that would violate current state and local requirements for social distancing, staying at home, and traveling for essential services only.

C. LTC Facilities and COVID-19

Long-term care facilities, a category that includes Medicare SNFs and Medicaid nursing facilities (NFs), must meet the consolidated Medicare and Medicaid requirements for participation (requirements) for LTC facilities (42 CFR part 483, subpart B) that were first published in the **Federal Register** on February 2, 1989 (54 FR 5316). These regulations have been revised and added to since that time, principally as a result of legislation or a need to address specific issues. The requirements were comprehensively reviewed and updated in

October 2016 (81 FR 68688), including a comprehensive update to the requirements for infection prevention and control.

Since the onset of the PHE, we have revised the requirements for LTC facilities through two interim final rules with comment periods (IFCs) to establish reporting and testing requirements specific to the mitigation of the current pandemic. The first IFC was the “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” interim final rule with comment, which appeared in the May 8, 2020 Federal Register (85 FR 27550) with an effective date of May 8, 2020 (hereafter referred to as the “May 8th COVID-19 IFC”).¹² The May 8th COVID-19 IFC established requirements for LTC facilities to report information related to COVID-19 cases among facility residents and staff. We received 299 public comments in response to the May 8th COVID-19 IFC. About 161, or over one-half of those comments, addressed the requirement for COVID-19 reporting for LTC facilities set forth at § 483.80(g). The second IFC was the “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” interim final rule with comment, which appeared in the September 2, 2020 Federal Register (85 FR 54820) with an effective date of September 2, 2020 (hereafter referred to as the “September 2nd COVID-19 IFC”).¹³ The September 2nd COVID-19 IFC strengthened CMS’ ability to enforce compliance with LTC reporting requirements and established a new requirement for LTC facilities to test facility residents and staff for COVID-19. We received 171 public comments in response to the September 2nd COVID-19 IFC, of which 113 addressed the requirement for COVID-19 testing of LTC facility residents and staff set forth at § 483.80(h).

¹² <https://www.federalregister.gov/documents/search?conditions%5Bterm%5D=85FR27550#>

¹³ <https://www.federalregister.gov/documents/search?conditions%5Bterm%5D=85FR54820#>

Health care inequities faced by the general population, discussed further in Section I.D. of this rule, are also seen within LTC facilities. Despite the increased use of nursing homes by minority residents, nursing home care remains highly segregated. Compared to Whites, racial/ethnic minorities tend to be cared for in facilities with limited clinical and financial resources, low nurse staffing levels, and a relatively high number of care deficiency citations.¹⁴ Nursing homes with relatively high shares of Black or Hispanic residents were more likely to report at least one COVID-19 death than nursing homes with lower shares of Black or Hispanic residents.¹⁵

D. Current COVID-19 Vaccination Activities in LTC Facilities and ICFs-IID

Because of the expedient development of COVID-19 vaccines and their authorization for emergency use by the U.S. Food and Drug Administration (FDA), the requirements for LTC facilities and Conditions of Participation (CoPs) for ICFs-IID do not currently address issues of resident and staff vaccination education, or reporting COVID-19 vaccinations or therapeutic treatments to CDC. Nonetheless, many facilities across the country are educating staff, residents, and resident representatives; participating in vaccine distribution programs; and voluntarily reporting vaccine administration. However, participation in these efforts is not universal and we are concerned that many groups at higher risk of infection, specifically residents and clients of LTC facilities and ICFs-IID, are not able to access COVID-19 vaccination. While all nursing homes across the U.S. (whether or not certified as a Medicare or Medicaid provider) were invited to participate in the COVID-19 vaccination Pharmacy Partnerships (discussed further in section II.A.1. of this rule), internal CDC data show that approximately 2,500 Medicare or Medicaid-certified LTC facilities (approximately 16 percent) did not participate in the Pharmacy Partnership program.

¹⁴ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.0094>

¹⁵ <https://www.kff.org/070b9a9/>

Given the congregate living models of LTC facilities and ICFs-IID, and the higher risk nature of their residents and clients due to age, comorbidities, and disabilities, people living and working in these facilities are at high risk of COVID-19 outbreaks, with residents and clients seeing higher rates of incidence, morbidity, and mortality than the general population. Data submitted to CDC's NHSN and posted on data.cms.gov for the week ending April 11, 2021 shows cumulative totals of 647,754 LTC resident COVID-19 confirmed cases and 131,926 LTC resident COVID-19 confirmed deaths. Also, there have been at least 569,502 total LTC staff COVID-19 confirmed cases and 1,888 total LTC staff COVID-19 confirmed deaths, on a cumulative basis. While we do not currently have data regarding the incidence of COVID-19 cases in ICFs-IID, we believe that these facilities may have also experienced significant rates of infection and that these data are likely an underestimate. A FAIR Health study examined the relationship between preexisting comorbidities of COVID-19 and mortality in privately insured individuals as reported in a white paper, Risk Factors for COVID-19 Mortality among Privately Insured Patients: A Claims Data Analysis.¹⁶ The paper states that there are several possible reasons for the high COVID-19 mortality risk in people with developmental disorders and intellectual disabilities. These include greater prevalence of comorbid chronic conditions. We seek information from the public regarding the epidemiologic burden of COVID-19 on ICFs-IIDs, reporting COVID-19 data by ICFs-IID, existing barriers to reporting, and ways to enhance and encourage voluntary reporting of COVID-19-related data to CDC's NHSN reporting module.

We also request comment on inequities in COVID-19 preventive care that may have been experienced by LTC facility residents and ICF-IID clients. This IFC aims to ensure that all LTC facility residents, ICF-IID clients, and the staff who care for them, are provided with ongoing

¹⁶ <https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/Risk%20Factors%20for%20COVID-19%20Mortality%20among%20Privately%20Insured%20Patients%20-%20A%20Claims%20Data%20Analysis%20-%20A%20FAIR%20Health%20White%20Paper.pdf>

access to vaccination against COVID-19. The accountable entities responsible for the care of residents and clients of LTC facilities and ICFs-IID must proactively pursue access to COVID-19 vaccination due to a unique set of challenges that generally prevent these residents and clients from independently accessing the vaccine. These challenges create potential disparities in vaccine access for those residing in LTC facilities and ICFs-IID. CDC has recommended states place LTC facility residents and health care personnel into Phase 1a.¹⁷ Despite their inclusion in most states' tier 1 vaccine priority category, it is CMS's understanding that very few individuals who are residents of LTC facilities are likely able to independently schedule or travel to public offsite vaccination opportunities. People reside in LTC facilities and ICFs-IID because they need ongoing support for medical, cognitive, behavioral, and/or functional reasons. Because of these issues, they may be less capable of self-care, including arranging for preventive health care. Independent scheduling and traveling off-site may be especially challenging for people with low health literacy, intellectual and developmental disabilities, dementia including Alzheimer's disease, visual or hearing impairments, or severe physical disability. This situation is particularly concerning because people with intellectual or developmental disabilities are at a disproportionate risk of contracting COVID-19.¹⁸

Similarly, there are large subpopulations of Americans who experience inequities on a regular basis in accessing quality health care beyond COVID-19 vaccination. Certain groups experience health and health care inequity, such as racial and ethnic minorities; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; people with disabilities; people living in rural areas; and others.

The COVID-19 pandemic has exacerbated these health care inequities as the country faces a convergence of economic, health, and climate crises.¹⁹ Historical patterns of inequity in

¹⁷ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations.html>

¹⁸ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-developmental-disabilities.html>

¹⁹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>

health care may persist despite the emphasis of public health officials on the need for equitable access to and utilization of preventive measures. Inequities have persisted through the COVID-19 PHE, with racial and ethnic minorities continuing to have higher rates of infection and mortality.²⁰ Ensuring that all residents, clients, and staff of LTC facilities and ICFs-IID have access to COVID-19 vaccinations seeks to address some of those inequities and provide timely protection for these individuals.

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 PHE. This rule establishes penalties for non-compliance, in order to require facilities to educate about and offer vaccination to residents and staff.

Based on the current rate of incidence of COVID-19 disease and deaths among LTC residents, we believe more action can be taken to help staff and residents avoid contracting SARS-CoV-2. LTC facility staff are also at risk of transmitting SARS-CoV-2 to residents, experiencing illness or death as a result of COVID-19 themselves, and transmitting it to their families, friends, unpaid caregivers and the general public. Asymptomatic people with SARS-CoV-2 may move in and out of the LTC facility and the community, putting residents and staff at risk of infection. Routine testing of LTC residents and staff, along with visitation restrictions, personal protective equipment (PPE) usage, social distancing, and vaccination for residents and staff are all part of CDC's Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes.²¹ COVID-19 vaccines are a crucial tool for slowing the spread of disease and death among both residents, staff, and the general public. Based on the Food and Drug Administration's (FDA) review, evaluation of the data, and their decision to authorize three vaccines for emergency use, we recognize that these vaccines meet

²⁰ <https://tcf.org/content/commentary/even-nursing-homes-covid-19-racial-disparities-persist/?agreed=1>

²¹ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>

FDA's standards for an emergency use authorization (EUA) for safety and effectiveness to prevent COVID-19 disease and related serious outcomes, including hospitalization and death. The combination of vaccination, universal source control (wearing masks), social distancing, and hand-washing offers further protection from COVID-19.²²

Similar to LTC facilities, due to the recent development and authorization of COVID-19 vaccines, the conditions of participation for ICF-IIDs do not currently address issues of client and staff vaccine education. Many CMS-certified ICFs-IID across the country are educating staff, clients, and client representatives, and 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 preventive care services.

E. COVID-19 PHE and Vaccine Development

Ensuring that LTC residents, ICF-IID clients, and staff have the opportunity to receive COVID-19 vaccinations will help save lives and prevent serious illness and death. On December 1, 2020, the Advisory Committee in Immunization Practices (ACIP) met and provided recommendations; CDC adopted ACIP's recommendation: that health care personnel and long-term care facility residents be offered COVID-19 vaccination first (Phase 1a).²³

All COVID-19 vaccines currently authorized for use in the United States were tested in clinical trials involving tens of thousands of people and met FDA's standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization. The clinical trials included participants of different races, ethnicities, and ages, including adults over the age of 65.²⁴ The most common side effects following vaccination are dependent on the specific vaccine that an individual receives, but the most common may include pain at the injection site, tiredness, headache, muscle pain, nausea, vomiting, fever, and chills.²⁵ After a

²² <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>

²³ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm>

²⁴ <https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-diversity-within-covid-19-vaccine-clinical-trials-key-questions-and-answers/>

²⁵ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>

review of all available information, ACIP and CDC have determined the lifesaving benefits of COVID-19 vaccination outweigh the risks or possible side effects.²⁶

The COVID-19 vaccines currently authorized for use in the United States require either a single dose or a series of two doses given three to four weeks apart. Every person who receives a COVID-19 vaccine receives a vaccination record card noting which vaccine and the dose received. Vaccine materials specific to each vaccine are located on CDC and FDA websites. CDC has posted a LTC facility toolkit “Preparing for COVID-19 Vaccination at your Facility” at <https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/>. This toolkit provides LTC administrators and clinical leadership with information and resources to help build vaccine confidence among residents, clients, and staff. CDC has also posted an ICF-IID toolkit “Toolkit for people with Disabilities” at <https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/people-with-disabilities.html>. This toolkit provides guidance and tools to help people with disabilities and paid and unpaid caregivers make decisions, help protect their health, and communicate with their communities.

While we are not requiring participation, we encourage individual residents, clients, and staff who use smartphones to use CDC’s new smartphone-based tool called v-safe After Vaccination Health Checker (v-safe) to self-report on one’s health after receiving a COVID-19 vaccine. V-safe is a new program that differs from the Vaccine Adverse Event Reporting System (VAERS), which we discuss in the section I.F. of this rule. Individuals may report adverse reactions to a COVID-19 vaccine to either program. Enrollment in v-safe allows individuals to directly report to CDC any problems or adverse reactions after receiving the vaccine. When an individual receives the vaccine, they should also receive a v-safe information sheet telling them how to enroll in v-safe. Individuals who enroll will receive regular text messages directing them to surveys where they can report any problems or adverse reactions

26 See Centers for Disease Control and Prevention. Benefits of Getting a COVID-19 Vaccine. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html>. Updated January 5, 2021. Accessed January 14, 2021.

after receiving a COVID-19 vaccine, as well as receive reminders for a second dose if applicable.²⁷ We note again that participation in v-safe is not mandatory, and further that individual participation is not traced to or shared with specific health care providers.

F. FDA & Emergency Use Authorization (EUA) of COVID-19 Vaccines

The FDA provides scientific and regulatory advice to vaccine developers and undertakes a rigorous evaluation of the scientific information through all phases of clinical trials; such evaluation continues after a vaccine has been licensed by FDA or authorized for emergency use.

CMS recognizes the gravity of the current public health emergency and the importance of facilitating availability of vaccines to prevent COVID-19. An EUA (authorized under section 564 of the Federal Food, Drug, and Cosmetic Act) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. The FDA may authorize certain unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.²⁸

VAERS is a safety and monitoring system that can be used by anyone to report adverse events with vaccines. While the COVID-19 vaccines are being used under an EUA, vaccination providers, manufacturers, and EUA sponsors must, in accordance with the National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. 300aa-1 to 300aa-34), report select adverse events to VAERS (that is, serious adverse events, cases of multisystem inflammatory syndrome (MIS), and COVID-19 cases that result in hospitalization or death).²⁹ Providers also must adhere to any revised safety reporting requirements. FDA's EUA website includes letters of

²⁷ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

²⁸ <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

²⁹ Department of Health and Human Services. VAERS – Vaccine Adverse Event Reporting System. Accessed at <https://vaers.hhs.gov/>. Accessed on January 26, 2021.

authorization and fact sheets and these should be checked for any updates that may occur. Additional adverse events following vaccination may be reported to VAERS. Adverse events will also be monitored through electronic health record- and claims-based systems (that is, CDC's Vaccine Safety Datalink and Biologicals Effectiveness and Safety (BEST)). On December 11, 2020, the U.S. Food and Drug Administration issued the first EUA for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The EUA allows the Pfizer-BioNTech COVID-19 vaccine to be distributed in the U.S. FDA has now issued EUAs for three vaccines for the prevention of COVID-19, to Pfizer (December 11, 2020) (16 years of age and older), Moderna (December 18, 2020) (18 years of age and older), and Johnson & Johnson's Janssen (February 27, 2021) (18 years of age and older). Fact sheets for healthcare providers administering vaccine are available for each vaccine product from the FDA.³⁰

FDA is closely monitoring the safety of the COVID-19 vaccines authorized for emergency use. The vaccination provider is responsible for mandatory reporting to VAERS of certain adverse events as listed on the Health Care Provider Fact Sheet. The requirements for LTC facilities and ICFs-IID established by this IFC can be met by offering current and future COVID-19 vaccines authorized by FDA under EUA, or any COVID-19 vaccines licensed by FDA, as well as any COVID-19 vaccine boosters if authorized or licensed. We note that at this time, some LTC facility residents and ICF-IID clients may not be eligible to receive vaccination due to age (that is, they are younger than 16), but we anticipate that they may become eligible for vaccination if authorized use of COVID-19 vaccines is expanded in the future.

II. Provisions of the Interim Final Rule

³⁰ <https://www.fda.gov/media/144637/download>, <https://www.fda.gov/media/144413/download>, <https://www.fda.gov/media/146304/download>

In order to help protect LTC residents and ICF-IID clients from COVID-19, each facility must have a vaccination program that meets the educational and information needs of each resident, resident representative, client, parent (if the client is a minor) or legal guardian, and staff member. The program should provide COVID-19 vaccines, when available, to all residents and staff who choose to receive them. Consistent vaccination reporting by LTC facilities via the NHSN will help to identify LTC facilities that have potential issues with vaccine confidence or slow uptake among either residents or staff or both. The NHSN is the Nation's most widely used health care-associated infection (HAI) tracking system. It furnishes states, facilities, regions, and the Government with data regarding problem areas and measures of progress. CDC and CMS use information from NHSN to support COVID-19 vaccination programs by focusing on groups or locations that would benefit from additional resources and strategies that promote vaccine uptake. CMS Federal surveyors and state agency surveyors will use the vaccination data in conjunction with the reported data that includes COVID-19 cases, resident deaths, staff shortages, PPE supplies and testing. This combination of reported data is used by surveyors to determine individual facilities that need to have focused infection control surveys. Facilities having difficulty with vaccine acceptance can be identified through examining trends in NHSN data; and the Quality Improvement Organizations (QIOs), groups of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare, can provide assistance to increase vaccine acceptance. Specifically, QIOs may provide assistance to LTC facilities by targeting small, low performing, and rural nursing homes 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 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; and assisting providers with reporting vaccinations accurately.

As discussed in detail below, we are revising the LTC facility requirements to specify that facilities must educate all residents and staff about COVID-19 vaccines, offer vaccination to all residents and staff, and report certain data regarding vaccination and therapeutic treatments to CDC via NHSN. Likewise, we are revising the ICF-IID Conditions of Participation to require that facilities must educate all clients and staff about COVID-19 vaccines and offer vaccination to all clients and staff. Reporting is not required for the ICFs-IID, however we strongly encourage voluntary reporting.

Immunization education, delivery, and reporting for influenza and pneumococcal vaccines are already a routine part of LTC facilities' infection control and prevention plans. We also require LTC facilities to offer education on influenza and pneumococcal vaccines and to give the resident or the resident representative the opportunity to accept or refuse vaccine.³¹ LTC facilities must document a resident's uptake or refusal of influenza and pneumococcal immunization in the resident's medical record and report through a different electronic submission system, the Minimum Data Set (MDS). In order to standardize COVID-19 infection control and prevention in LTC facilities, we are issuing these requirements for facilities to provide COVID-19 vaccine education, offer COVID-19 vaccination, and report COVID-19 vaccinations for LTC facility residents and staff.

We require ICFs-IID to provide or obtain health care services for clients, including immunization, using as a guide the recommendations of the CDC Advisory Committee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.³² While the ICF-IID CoPs do not currently address specific vaccinations, the unprecedented risk of COVID-19 illness demands specific attention to protect clients. As discussed in section B.3. of this IFC, we are not issuing COVID-19 vaccination reporting requirements for ICFs-IID at this time due to current low rates of participation in

³¹ § 483.80(d)

³² <https://pediatrics.aappublications.org/content/145/3/e20193995>

NHSN by ICFs-IID and the delays that would be incurred by equipment acquisition (in some facilities) and NHSN enrollment, verification, and training.

A. Long-Term Care Facilities

1. Offer and Provide Vaccine to LTC Residents and Staff

With this IFC, we are amending the requirements at § 483.80 to add a new paragraph (d)(3). We require at new § 483.80(d)(3)(i) that LTC facilities develop and implement policies and procedures to ensure that they offer residents and staff vaccination against COVID-19 when vaccine supplies are available. We note that we are permitting but not requiring LTC facilities to provide the vaccine directly. They may also provide it indirectly, such as through arrangement with a pharmacy partner or local health department. Implementation of COVID-19 vaccine education and vaccination programs in LTC facilities will protect residents and staff, allowing for an expedited return to more normal routines, including timely preventive health care; family, caregiver, and community visitation; and group and individual activities. While we require that all residents and staff must be educated about the vaccine, we note that in situations, for example, where an individual has already received a COVID-19 vaccine or has a known medical contraindication (that is, an allergy to vaccine ingredients or previous severe reaction to a vaccine), the facility is not required to offer vaccination to that person. CDC has posted “Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States” describing these clinical situations.³³ CDC advice and guidance documents are periodically updated to reflect the latest information, and we cite this as an example, not as a regulatory requirement. At § 483.70(i)(1), in accordance with accepted professional standards and practices, the LTC facility must maintain medical records on each resident that are complete and accurately documented. In order to maintain current information, refusal of a vaccine should be documented with the reason; if the resident received the vaccine(s) elsewhere that should also be documented.

³³ <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

CDC established the Pharmacy Partnership for Long-term Care Program (Pharmacy Partnership), a national distribution initiative that provides end-to-end management of the COVID-19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of certain reporting requirements, to facilitate safer vaccination of the LTC facility population (residents and staff), while reducing burden on LTC facilities and jurisdictional health departments.³⁴ Most LTC facility staff who had not received their COVID-19 vaccine elsewhere, or needed to complete a vaccine series, were also vaccinated as part of the program. At the time of publication, we do not have data on the Partnership accomplishments in vaccinating residents or staff, but as discussed in the Regulatory Impact Analysis (RIA) section of this rule, there is extensive turnover in both groups, establishing the need for ongoing vaccination policies and programs.

The Pharmacy Partnership is currently facilitating safe vaccination of some LTC facility residents and staff, while reducing the burden on LTC facilities. The facilities remain responsible for the care and services provided to their residents. CDC has expected pharmacy partners to provide program services on-site at participating facilities for approximately two months from the date of each facility's first vaccination clinic, concluding in all facilities by spring of 2021. Internal CDC data shows that 99 percent of participating SNFs had held their third (final) clinic as of March 15, 2021. As the Pharmacy Partnership for LTC program comes to an end, it is important to ensure facilities have policies and procedures to provide continued access to COVID-19 vaccine for new or unvaccinated residents and staff, groups that will each exceed in magnitude over the course of this year a number larger than those offered vaccination during the Partnership's tenure. The Federal Government has also launched the Federal Retail Pharmacy Program, a collaboration between the Federal Government, states, and territories, and 21 national pharmacy partners and independent pharmacy networks representing over 40,000 pharmacies

³⁴ <https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html> and provide additional information on vaccination under this program: <https://covid.cdc.gov/covid-data-tracker/#vaccinations-ltc>

nationwide, including LTC facility pharmacy locations. This collaboration is intended to enhance the opportunities for vaccine uptake in congregate living settings.

For residents and staff who opt to receive the vaccine, vaccination must be conducted in a safe and sanitary manner in accordance with § 483.80; and as required by the vaccine provider agreements, COVID-19 vaccination clinics must be conducted in a manner for safe delivery of vaccines during the COVID-19 pandemic.³⁵ All facilities must adhere to current CDC infection prevention and control (IPC) recommendations. Screening individuals for currently suspected or confirmed cases of COVID-19, previous allergic reactions, and administration of therapeutic treatments and services is important for determining whether these individuals are appropriate candidates for vaccination at any given time. According to current CDC guidelines, anyone infected with COVID-19 should wait until infection resolves and they have met the criteria for discontinuing isolation.³⁶ We note that indications and contraindications for COVID-19 vaccination are evolving, and LTC facility Medical Directors and Infection Preventionists (IPs) should be alert to any new or revised guidelines issued by CDC, FDA, vaccine manufacturers, or other expert stakeholders.

Staff at LTC facilities should follow the recommended IPC practices described on CDC's website for LTC facilities.³⁷ For example, the website currently has "Long-Term Care Facility Toolkit: Preparing for COVID-19 in LTC facilities"³⁸ and the "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic."³⁹ These recommendations, which emphasize close monitoring of residents of long-term care facilities for symptoms of COVID-19, universal source control, physical distancing, hand hygiene, and optimizing engineering controls, are intended to help protect staff and residents from exposure.

³⁵ <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>

³⁶ Interim Guidance on Duration of Isolation and Precautions for Adults with COVID-19 | CDC, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

³⁷ <https://www.cdc.gov/longtermcare/>

³⁸ <https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/>

³⁹ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

Administration of any vaccine includes appropriate monitoring of vaccine recipients for adverse reactions. CDC has information describing IPC considerations for residents of long-term care facilities with systemic signs and symptoms following COVID-19 vaccination. See “Post-Vaccine Considerations for Residents,” located at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html>. This information is also included on FDA fact sheets. Long-term care facilities must have strategies in place to appropriately evaluate and manage post-vaccination signs and symptoms of adverse events among their residents.

CDC advises that COVID-19 vaccination providers document vaccine administration in their medical records system within 24 hours of administration and report administration data as specified in their vaccine provider agreements and to applicable local vaccine tracking programs (that is, Immunization Information System) as soon as practicable and no later than 72 hours after administration. While LTC facility staff may not have personal medical records on file with the employing LTC facility, all staff COVID-19 vaccinations must be appropriately documented by the facility in a manner that enables the facility to report in accordance with this rule (that is, in a facility immunization record, personnel files, health information files, or other relevant document). Updates to CDC’s COVID-19 Vaccination Program Provider Agreement Requirements can be located on CDC’s website.⁴⁰

2. COVID-19 Disease and Vaccine Education

a. LTC Facility Staff

Given the new and emerging nature of COVID-19 disease, vaccines, and treatments, we recognize that education is critical. With this IFC, we are amending the requirements at § 483.80 to add new paragraph (d)(3)(ii) to require that LTC facility staff are educated about vaccination against COVID-19. LTC facility staff are integral to the function of LTC facilities and the health

⁴⁰ Centers for Disease Control and Prevention. CDC COVID-19 Vaccination Program Provider Requirements and Support. Accessed at <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>. Accessed on January 26, 2021.

and well-being of residents. For the purposes of COVID-19 vaccine education, offering, and reporting, we consider LTC facility staff to be those individuals who work in the facility on a regular (that is, at least once a week) basis. 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. We also note that this description of staff differs from that in § 483.80(h), established for the LTC facility COVID-19 testing requirements in the September 2nd, 2020 COVID-19 IFC. This rule’s description of LTC facility staff is limited to individuals working in the facility on a regular (at least weekly) basis, while the definition set out at § 483.80(h) includes workers who come into the facility infrequently, such as a plumber who may come in only a few times per year. We considered applying the § 483.80(h) definition to the vaccination and reporting requirements in this rule, but public feedback tells us the definition in paragraph (h) was overbroad for these purposes. Stakeholders report that there are many LTC facility staff and individuals providing occasional services under arrangement, and that the requirements may be excessively burdensome for the facilities to apply the definition at paragraph (h) because it includes many individuals who have very limited, infrequent contact with facility staff and residents. Stakeholders also report that providing the required education and offering vaccination to these individuals who may only make unscheduled visits to the facility would be extremely burdensome. That said, the description in this rule—individuals who work in the facility on a regular (that is, at least once a week) basis—still includes many of the individuals included in paragraph (h). In addition to facility-employed personnel, many facilities have services provided on-site, on a regular basis by individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, or volunteers. Any of these individuals who provide services on-site at least weekly would be included in “staff” who must be educated and offered the vaccine as it becomes available. As established by this rule at § 483.80(d)(3), LTC facilities 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 vaccination to all individuals who provide services less frequently.

There are also individuals who may enter the facility for specific purposes and for a limited amount of time, such as delivery and repair personnel, or volunteers who may enter the LTC facility infrequently (less than once a week). We believe it would be overly burdensome to mandate that each LTC facility educate and offer the COVID-19 vaccine to all individuals who enter the facility. However, while facilities are not required to educate and offer vaccination to these individuals, they may choose to extend their education and offering efforts beyond those persons that we consider to be staff for purposes of this rulemaking. We do not intend to prohibit such extensions and encourage facilities to educate and offer vaccination to these individuals as reasonably feasible.

We recognize that facilities may choose to use a broader definition of “staff.” We note that CDC defines “staff” in the NHSN as: ancillary service employees, nurse employees, aide, assistant and technician employees, therapist employees, physician and licensed independent practitioner employees and other health care providers. Categories are further broken down into environmental, laundry, maintenance, and dietary services; registered nurses and licensed practical/ vocational nurses; certified nursing assistants, nurse aides, medication aides, and medication assistants; therapists (such as respiratory, occupational, physical, speech, and music therapist) and therapy assistants; physicians, residents, fellows, advanced practice nurses, and physician assistants; and persons not included in the employee categories listed, regardless of clinical responsibility or patient contact, including contract staff, students, and other non-employees.⁴¹

We are requiring that LTC facility staff (that is, individuals who work in the facility on a regular basis) be educated about the benefits and risks and potential side effects of the COVID-

⁴¹ <https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html>

19 vaccine. Educating staff further about the development of the vaccine, how the vaccine works, and the particulars of the multi-dose vaccine series is encouraged but not required. Broader understanding of the vaccine will support the national effort to vaccinate against COVID-19. Staff should be instructed about the importance of vaccination for residents, their personal health, and community health. Better understanding the value of vaccination may allow staff to appropriately educate residents and residents' family members and unpaid caregivers about the benefits of accepting the vaccine. While most residents in LTC facilities are isolated from the broader community during the PHE, staff travel to and from the facility and the community, presenting risks of transmitting the virus to or from residents, family members, other caregivers, and the public.

We note that for LTC facilities that participated in the Federal Pharmacy Partnership for Long-Term Care Program, pharmacies worked directly with LTC facilities to ensure staff who received the vaccine also received an EUA fact sheet before vaccination. The EUA fact sheet explains the risks and possible side effects and benefits of the COVID-19 vaccine they are receiving and what to expect.

Staff education must cover the benefits of vaccination, which typically include reduced risk of COVID-19 illness and related serious COVID-19 outcomes, including hospitalization and death, the bolstered protection offered by completing a full series of multi-dose vaccines if used, and other benefits identified as research continues. Early data also suggests that vaccination offers reduced risk of inadvertently transmitting the virus to patients and other contacts.⁴² Staff education must also address risks associated with vaccination, which should include potential side-effects of the vaccine, including common reactions such as aches or fever, and rare reactions such as anaphylaxis.⁴³ The low likelihood of severe side effects should be included in this education. If other benefits or risks or possible side-effects are identified in the future, whether

⁴² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html>

⁴³ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>

through research, or authorization or licensing of new COVID-19 vaccines, those facts should be incorporated into education efforts. Staff should also be informed about ongoing opportunities for vaccination, if they miss a Pharmacy Partnership clinic, for example, or initially declined vaccination but later decide to accept the vaccine. In addition to ongoing education and informational updates for all staff members, we expect that new staff will receive appropriate education on COVID-19 vaccines.

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 Medical Director and, and use CDC and FDA resources as sources of information for their vaccination education initiatives. The LTC Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility has information and resources to build confidence among staff and residents.⁴⁴ The FDA provides materials for industry and other stakeholder specific to the EUA process and the vaccines.⁴⁵ Examples of educational and training topics include engaging residents in effective COVID-19 vaccine conversations, answering questions about consent for vaccine, common side effects, educating residents and staff about what to expect after vaccination, and the importance of maintaining infection prevention and control practices after vaccination. Each vaccine manufacturer is also developing educational and training resources for its individual vaccine. Building vaccine understanding broadly among staff, residents, and resident representatives, as well as dispelling vaccine misinformation and spreading information about successes in the program are critical to improving vaccine uptake rates, with potential for reducing vaccine hesitancy and the spread of misinformation.

The facility's vaccination policies and procedures must be part of the IPC program. Facilities can determine where they keep the documentation that demonstrates educational

⁴⁴ <https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/>

⁴⁵ <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

efforts and offering the vaccine to staff. Some examples of evidence of compliance may include sign in sheets, descriptions of materials used to educate, summary notes from all-staff question and answer sessions. There may be posters and flyers announcing appointments for vaccine clinic days or other opportunities to be vaccinated.

b. LTC Facility Residents and Resident Representatives

With this IFC, we are amending the requirements at § 483.80 to add a new paragraph (d)(3)(iii) to require that LTC facility residents or resident representatives are educated about vaccination against COVID-19. Explaining the risks and possible side effects and benefits of any treatments to a resident or their representative in a way that they can understand is the standard of care, and a patient right as specified at § 483.10(c)(5). In LTC facilities, consent or assent for vaccination should be obtained from residents and/or their representatives as appropriate and documented in the resident's medical record. The residents or their representatives have the right to decline the vaccine, based on the resident's rights requirement at § 483.10(c)(5) (regarding the resident's right to be informed of risks and benefits of proposed care). It is important to talk to residents and representatives to learn why they may be declining vaccination on their own behalf, or on behalf of the resident, and tailor any educational messages accordingly. Residents may not be forced or required to be vaccinated if the person or their representative declines.

Resident representatives must be included as a component of the LTC facility's vaccine education plan, as the resident representatives may be called upon for consent and/or may be asked to assist in promoting vaccine uptake of the resident, as appropriate. We note that for LTC facilities participating in the Federal Pharmacy Partnership for Long-term Care Program, pharmacies will work directly with LTC facilities to ensure residents who receive the vaccine also receive an EUA fact sheet before vaccination. The EUA fact sheet explains the risks or potential side effects and benefits of the COVID-19 vaccine they are receiving and what to expect.

In addition to the topics addressed above for education of LTC facility staff, education of residents and resident representatives should cover that, at this time while the U.S. Government is purchasing all COVID-19 vaccine in the United States for administration through the CDC COVID-19 Vaccination Program, all LTC facility residents are able to receive the vaccine without any copays or out-of-pocket costs. The provider agreements for the CDC COVID-19 Vaccination Program specifically prohibit charging out-of-pocket fees to the vaccine recipient. Medicare pays for the administration of the COVID-19 vaccine to beneficiaries, and other public and private insurance providers are required to cover it as well. To ensure broad access to a vaccine for America's Medicare beneficiaries, CMS published an Interim Final Rule with Comment Period (IFC) on November 6, 2020, that implemented section 3713 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act which required Medicare Part B to cover and pay for a COVID-19 vaccine and its administration without any cost-sharing (85 FR 71142, November 6, 2020). Any vaccine that receives Food and Drug Administration (FDA) authorization, through an EUA, or is licensed under a Biologics License Application (BLA), will be covered under Medicare as a preventive vaccine at no cost to beneficiaries. The November 6th IFC also implemented section 3203 of the CARES Act that ensure swift coverage of a COVID-19 vaccine by most private health insurance plans without cost sharing from both in and out-of-network providers during the course of the PHE.⁴⁶ The Provider Relief Fund Uninsured Program will also reimburse for administration of COVID-19 vaccine to individuals who are uninsured.⁴⁷

Education for residents and representatives must also provide the opportunity for follow-up questions and be conducted in a manner that is reasonably understood by the resident and the representatives.

⁴⁶ 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).

⁴⁷ <https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html>

3. LTC Facility Reporting

With this IFC, we are amending the requirements at § 483.80(g) to require that LTC facilities report to NHSN, on a weekly basis, the COVID-19 vaccination status and related data elements of all residents and staff. The data to be reported each week will be cumulative, that is, data on all residents and staff, including total numbers and those who have received the vaccine, as well as additional data elements. In this way, the vaccination status of every LTC facility will be known on a weekly basis. Data on vaccine uptake will be important to understanding the impact of vaccination on SARS-CoV-2 infections and transmission in nursing homes.⁴⁸ This understanding, in turn, will help CDC make changes to guidance to better protect residents and staff in LTC facilities. In addition, LTC facilities must also report any COVID-19 therapeutics administered to residents. CDC has currently defined “therapeutics” for the purposes of the NHSN as a “treatment, therapy, or drug” and stated that monoclonal antibodies are examples of anti-SARS-CoV-2 antibody-based therapeutics used to help the immune system recognize and respond more effectively to the SARS-CoV-2 virus.

LTC administrators and clinical leadership are encouraged to track vaccination coverage in their facilities and adjust communication with residents and staff accordingly. Facilities reporting vaccinations to the NHSN Long-Term Care Facility Component⁴⁹ or Healthcare Personnel Safety Component are encouraged to use the COVID-19 Vaccination module to track aggregate vaccination coverage in their facility, which can help target education efforts, plan resource needs, and update visitation and cohorting policies (that is, grouping residents within the facility while waiting for COVID-19 test results or showing signs of illness) as indicated by evolving public health guidelines. NHSN data will allow CDC to determine the number and percentage of staff and residents in each facility who have received the COVID-19 vaccine.⁵⁰

⁴⁸ <https://www.cdc.gov/nhsn/pdfs/covid19/lctf/57.158-toi-508.pdf>

⁴⁹ Centers for Disease Control and Prevention - National Healthcare Safety Network. Surveillance for Weekly HCP & Resident COVID-19 Vaccination. Accessed at <https://www.cdc.gov/nhsn/lc/weekly-covid-vac/index.html>. Accessed on January 26, 2021.

⁵⁰ <https://www.cdc.gov/nhsn/lc/weekly-covid-vac/index.html>

Our intent in mandating reporting of COVID-19 vaccines and therapeutics to NHSN is in part to monitor broader community vaccine uptake, but also to allow CDC to identify and alert CMS to facilities that may need additional support in regards to vaccine education and administration. These specific data collections replace and refine the current requirement, set out at § 483.80(g)(1)(viii), based on the opportunities presented by the development and authorization of COVID-19 vaccines and therapeutic treatments. If we identify a need to collect other specific data related to COVID-19, we will do this through appropriate rulemaking. The information reported to CDC in accordance with § 483.80(g) will be shared with CMS and we will retain and publicly report this information to support protecting the health and safety of residents, staff, and the general public, in accordance with sections 1819(d)(3)(B) and 1919(d)(3) of the Act.

Aggregate COVID-19 vaccination data collected as a result of this rulemaking will be made available to the public in the future. We note that until that time, individuals may request data per the Freedom of Information Act (FOIA) (5 U.S.C. 552), which provides that, upon request from any person, a Federal agency must release any agency record unless that record falls within one of the nine statutory exemptions and three exclusions (see <https://www.foia.gov/faq.html> for detailed information). Further, FOIA requires that agencies make available for public inspection copies of records, which because of the nature of their subject matter, have become or are likely to become the subject of subsequent requests for substantially the same information. We have received, and expect to continue to receive, COVID-19-related FOIA requests. Facility influenza vaccine data are available through CMS's Care Compare tool because these data are collected directly through the MDS, which feeds into the Care Compare tool. Data submitted through NHSN concerning COVID-19 testing and cases in LTC facilities is publicly posted on data.cms.gov.⁵¹

⁵¹ <https://www.medicare.gov/care-compare/>

We are aware that COVID-19 vaccine information may be reported to local and state health departments, as well as by various pharmacy partners, and we believe direct submission of data by LTC facilities through NHSN will show actions and trends that can be addressed more efficiently on a national level. All state health departments and many local health departments already have direct access through NHSN to LTC facilities' COVID-19 data and are using the data for their own local response efforts. Thus, reporting in NHSN will, in many cases, serve the needs of state and local health departments. We request public comment on whether states are collecting COVID-19 vaccination data already, through other mechanisms.

National reporting through NHSN, which is limited to enrolled health care providers, will allow CDC to examine vaccination coverage compared with community infection rates, to determine visitation and other COVID-19 infection prevention and control guidelines, including cohorting. Currently, low rates of voluntary use of NHSN for vaccination reporting precludes accurate estimates of vaccine coverage. Regular and required reporting into the NHSN and familiarity with the NHSN process will also increase the future capacity of facilities to report if new pandemics or other threats arise in the future.

Pharmacy partners reported vaccination clinics they held in LTC facilities, and they have shared these data with CDC. Internal CDC data shows that 99 percent of participating SNFs had held their 3rd (final) clinic as of March 15, 2021. However, they have not continued to collect or report these data after their clinics concluded. Additionally, the pharmacy partners only collected numerator data (the number of residents and staff vaccinated), and not denominator data (the total number of residents and staff). Therefore, CDC cannot calculate the percentages of residents and staff vaccinated in each facility via the Federal Pharmacy Partnership data.

NHSN provides the long-term means to collect these data now that the Pharmacy Partnership has finished and will allow for calculation of percentages of residents and staff vaccinated in every facility. We anticipate that the additional reporting burden to LTC facilities will be minimal. All LTC facilities are already required, at § 483.80(g), to report certain

COVID-19 case and outcomes data to NHSN every week, and the new vaccination reporting is in the same NHSN reporting system they currently use. Finally, health departments for states, the District of Columbia, and territories all have access to NHSN data for their jurisdictions and can use these data to inform their own response efforts. Facilities can determine where they keep the documentation that should be collected so that they can comply with the NHSN COVID-19 vaccination reporting requirements for staff.

Therapeutic treatments for COVID-19 administered to LTC residents, such as those in the form of monoclonal antibodies delivered intravenously, must now also be reported through NHSN in accordance with new § 483.80(g)(1)(ix) so that CDC can appropriately monitor their use. This reporting of therapeutics requirement is similar to the requirement that hospitals must report information about therapeutics (85 FR 85866). Data on the use of therapeutics will be critical to help support allocation efforts to ensure that nursing homes have access to supplies and services to meet their needs. This requirement and burden will be submitted to OMB under OMB control number 0938-1363.

B. Intermediate Care Facilities for Individuals with Intellectual Disabilities

1. Offer and Provision of Vaccine to ICF-IID Clients and Staff

With this IFC, we are redesignating the current § 483.460(a)(4) to § 483.460(a)(5) and adding a requirement at new § 483.460(a)(4)(i) to require that ICFs-IID offer clients and staff vaccination against COVID-19 when vaccine supplies are available. The vaccine may be offered and provided directly by the ICF-IID or indirectly, such as through a local health department, pharmacy, or doctor's office. Vaccines may be administered onsite or at other appropriate locations. Implementation of COVID-19 education and vaccination programs in ICFs-IID will help protect clients and staff, allowing an eventual return to more normal routines, including timely preventive health care; family, caregiver and community visitors; and group and individual activities. While we require that all clients and staff must be educated about the vaccine, we note that in situations where an individual has already received the vaccine or has a

known medical contraindication (that is, an allergy to vaccine ingredients or previous severe reaction to a vaccine), the facility is not required to offer vaccination to that person.⁵²

The client, parent (if the client is a minor), or legal guardian (collectively, “representative”) has the right to refuse treatment based on the requirement at § 483.420(a)(2) that states the facility must ensure the rights of all clients. Therefore, the facility must inform each client and/or the representative regarding the client’s medical condition, developmental and behavioral status, attendant risks of treatment, and the right to refuse treatment. Clients and their representatives (on behalf of the client) have the right to refuse vaccination.

For clients and staff who opt to receive the vaccine, vaccination must be conducted in a sanitary manner in accordance with CDC, FDA, § 483.410(b) of the ICF-IID CoPs, and manufacturer guidelines. As required by the provider agreements, COVID-19 vaccination clinics must be conducted in a manner for safe delivery of vaccines during the COVID-19 pandemic.⁵³ All facilities should adhere to current CDC IPC recommendations. Screening individuals for suspected or confirmed cases of COVID-19, previous allergic reactions, and administration of therapeutic treatments is important for determining whether they are appropriate candidates for vaccination at any given time. According to current CDC guidelines, anyone infected with COVID-19 should wait until infection resolves and they have met the criteria for discontinuing isolation.⁵⁴ We note that indications and contraindications for COVID-19 vaccination are evolving, and the director of nursing (DON) or nursing staff of the facility should be alert to any new or revised guidelines issued by CDC, FDA, vaccine manufacturers, and other expert stakeholders.

Staff at ICFs-IID should follow the recommended IPC practices described on CDC’s website for ICFs-IID. For example, the website currently has documents entitled “Guidance for

⁵² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html>

⁵³ <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>

⁵⁴ Interim Guidance on Duration of Isolation and Precautions for Adults with COVID-19 | CDC, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

Group Homes for Individuals with Disabilities” and the “Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic”.^{55,56} These recommendations, which emphasize close monitoring of clients of group homes for individuals with disabilities or ICFs-IID for symptoms of COVID-19, universal source control, physical distancing, use of masks, hand hygiene, and optimizing engineering controls, are intended to protect staff, residents, and visitors from exposure to SARS-CoV-2.

Administration of any vaccine includes appropriate monitoring of vaccine recipients for adverse reactions. For the COVID-19 vaccines, safety monitoring is also being conducted.⁵⁷ CDC has information describing IPC considerations for residents of ICF-IIDs with systemic signs and symptoms following COVID-19 vaccination. See “Vaccine considerations for people with disabilities,” located at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/disabilities.html>. Post-vaccine considerations are listed out for consideration by ICFs-IID clinical staff. ICFs-IID must have strategies in place to appropriately evaluate and manage immediate post-vaccination adverse reactions among any individuals who are vaccinated on site, and risks and potential side effects of vaccination on clients.

CDC advises that COVID-19 vaccination providers should document vaccine administration in their medical records within 24 hours of administration and report administration data as specified in their vaccine provider agreements and to applicable local vaccine tracking programs (that is, Immunization Information System). While an ICF-IID is unlikely to be a COVID-19 vaccination provider, all vaccinations should be appropriately documented. While ICF-IID staff may not have personal medical records with the ICF-IID, ICFs-IID participating in voluntary NHSN reporting should appropriately document staff vaccinations in a manner that enables the facility to report in accordance with NHSN guidelines

⁵⁵ <https://www.cdc.gov/coronavirus/2019-ncov/community/group-homes.html>

⁵⁶ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

⁵⁷ <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance>

(that is, in a facility immunization record, personnel files, health information files, or other relevant documentation).

2. COVID-19 Disease and Vaccine Education

a. ICF-IID Staff

Given the new and emerging qualities of COVID-19 disease, vaccines, and treatments we recognize that education of clients and staff is critical. With this IFC, we are amending the conditions of participation at new § 483.460(a)(4)(ii) to require that ICF-IID staff are educated about vaccination against COVID-19. ICF-IID staff are integral to the function of the ICFs-IID and the health and well-being of clients. For the purposes of COVID-19 vaccine education and offering, we consider ICF-IID staff to be those individuals who work in the facility on a regular (that is, at least once a week) basis. We note that this includes those individuals who may not be physically in the ICF-IID for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. In addition to facility-employed personnel, many facilities have services provided on-site, on a regular basis by individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, behaviorists, mental health professionals, and volunteers. These individuals would be included in “staff” who must be educated and offered the vaccine as available.

There are also individuals who may enter the facility for specific purposes and for a limited amount of time, such as delivery and repair personnel, or volunteers who may enter the ICF-IID infrequently (meaning less than once weekly). We believe it would be overly burdensome to mandate that each ICF-IID educate and offer the COVID-19 vaccine to all individuals who enter the facility. However, while facilities are not required to educate and offer vaccination to these individuals, they may choose to extend their education and offering efforts beyond those persons that we consider to be “staff” for purposes of this rulemaking. We do not intend to prohibit such extensions and encourage facilities to educate and offer vaccination to these individuals as reasonably feasible.

We recognize that facilities may choose to use a broader definition of “staff.” We note that CDC categorizes staff in the NHSN as: ancillary service employees, nurse employees, aides, assistant and technician employees, therapist employees, physician and licensed independent practitioner employees and other health care providers. Categories are further broken down into environmental, laundry, maintenance, and dietary services; registered nurses (RNs) and licensed practical/ vocational nurses; certified nursing assistants, nurse aides, medication aides, and medication assistants; therapists (such as respiratory, occupational, physical, speech, and music therapists) and therapy assistants; physicians, residents, fellows, advanced practice nurses, and physician assistants; and persons not included in the employee categories listed, regardless of clinical responsibility or patient contact, including contract staff, students, and other non-employees.⁵⁸

For purposes of the CMS requirements related to COVID-19 education and vaccination issued in this rule, we believe that the NHSN definition may be impractical. In addition to regularly employed personnel, many facilities have services provided directly to residents under contract, such as physical therapy, occupational therapy, behavior therapy, case management, and mental health services. There are also individuals who may enter the facility for specific purposes and for a limited amount of time, such as delivery personnel, plumbers, and other vendors. Even regular volunteers may enter the ICF-IID infrequently. We do not believe that mandating these requirements for every individual who enters the facility at any time is necessary to protect the clients and staff. In addition, we believe it would be overly burdensome for the ICF-IID to educate and offer the COVID-19 vaccine to all individuals who enter the facility. Staff and resources are limited in ICFs-IID, and therefore staff may not be available to educate and offer the vaccine to every individual that enters.

We are requiring that ICF-IID staff (that is, individuals who are eligible to work in the facility on a routine, or at least once weekly, basis) be educated about the benefits and risks and

⁵⁸ <https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html>

potential side effects of the COVID-19 vaccine. Educating staff further about the development of the vaccine, how the vaccine works, and the particulars of multi-dose vaccine series is encouraged but not required. Broader understanding of the vaccine will support the national effort to vaccinate against COVID-19. Staff should be educated to help them understand the importance of vaccination for helping to safeguard clients, personal health, and broader community health. Better understanding of the value and safety of the vaccines will allow staff to appropriately educate clients and representatives about the benefits of accepting the vaccine.

Staff education must cover the benefits and risks or possible side effects of vaccination, which typically include reduced risk of COVID-19 illness, and related serious COVID outcomes, including hospitalization and death, the bolstered protection offered by completing a full series of multi-dose vaccines (if used), and other benefits identified as research and immunization continues. Staff education must also address risks associated with vaccination, which should include potential side-effects of the vaccine, including common reactions such as aches or fever, and rare reactions such as anaphylaxis. The low likelihood of severe side effects should be included in this education. If other benefits, risks, or side-effects are identified in the future, whether through research, or authorization or licensing of new COVID-19 vaccine products, those facts should be incorporated into education efforts. Staff should also be informed about ongoing opportunities for vaccination. Staff should be provided education on culturally appropriate ways to educate and share information with clients to prevent misinformation, confusion, or loss of credibility. In addition to ongoing education and informational updates for all staff members, we expect that new staff will be screened to determine vaccination status, and potential need for appropriate education on COVID-19 vaccines during their onboarding or orientation. 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 ICF-IID's Medical Director and use CDC resources as the source of information for their vaccination education initiatives. Each

manufacturer is also developing educational and training resources for its individual vaccine candidate. Building vaccine understanding broadly among staff, clients, and parent (if the client is a minor), or legal guardian or representative, as well as dispelling vaccine misinformation, are critical to vaccine uptake rates.

The facility vaccination policies and procedures must be developed as part of the COVID-19 immunization requirements at § 483.460(a)(4). Facilities can determine where they keep the documentation that demonstrates educational efforts and offering the vaccine to staff. Some examples of evidence of compliance may include sign in sheets, descriptions of materials used to educate, and summary notes from all-staff question and answer sessions. There may be posters and flyers announcing appointments for vaccine clinic days or other vaccination opportunities.

b. ICF-IID Clients

New § 483.460(a)(4)(iii) requires that ICF-IID clients, or their representatives are educated about vaccination against COVID-19. Explaining the risks and benefits of any treatments to a client or representative in a way that they understand is the standard of care. In ICFs-IID, consent or assent for vaccination should be obtained from clients or representatives and documented in the client's medical record. It is important to talk to clients and representatives to learn why they may be declining vaccination and tailor educational messages accordingly, that is, by addressing specific questions or concerns.

Clients of ICFs-IID and their representatives must be offered education about vaccine immunization development, administration, and evaluation. Representatives must be included as a component of the ICF-IID's vaccine education plan as the representatives may be called upon for consent and/or may be asked to assist in encouraging vaccine uptake by the client.

In addition to the topics addressed above for education of ICF-IID staff, education of clients and representatives should cover the fact that, at this time while the U.S. Government is purchasing all COVID-19 vaccine in the United States for administration through the CDC

COVID-19 Vaccination Program, all ICF-IID clients are able to receive the vaccine without any copays or out-of-pocket costs. Currently Medicaid pays for the administration of the COVID-19 vaccine to beneficiaries, and other public and private insurance providers are required to cover it as well.

Education for clients and representatives must also provide the opportunity for follow up questions, and be conducted in a manner that is reasonably understood by the clients and representatives. Information should be made available in accessible formats as appropriate for a facility's population. That is, educational materials and delivery must meet relevant standards in Section 504 of the Rehabilitation Act, which may include making such material available in large print, Braille, and American Sign Language, and using close captioning, audio descriptions, and plain language for people with vision, hearing, cognitive, and learning disabilities.

3. ICF-IID Voluntary Reporting

While there would be great value in collecting more data about COVID-19 incidence and vaccinations in ICFs-IID, we are not mandating such data submission at this time. Currently there are only approximately 80 ICFs-IID participating in the NHSN or any other formal reporting program, although there are opportunities for ICFs-IID to enroll. Requiring all ICFs-IID to report to NHSN would create a new field of administrative burden for ICFs-IID, potentially requiring new equipment, administrative staff, and training. Further, reporting through NHSN would require time, likely several weeks to months, for the facilities not yet participating in NHSN to complete enrollment with CDC and appropriately train those staff who would be responsible for data submission, effectively making compliance within the effective date of this IFC nearly impossible. Based on the information we have received from stakeholders, we do not believe that ICFs-IID are administering therapeutics at this time. We encourage voluntary reporting as facilities are able to do so.

C. Enforcement

Enforcement of the provisions of this IFC for LTC facilities will be similar to those requirements addressing influenza and pneumococcal vaccinations. We will impose civil money penalties if we determine that the facility has failed to report vaccination data.⁵⁹ Education and vaccine administration must be reflected in facility policies and procedures, as well as in staff and resident records. In addition, NHSN reporting of vaccine and therapeutics must be reflected in facility policies and procedures, with evidence of data submission. For ICFs-IID, education and administration of the vaccine must be reflected in facility policies and procedures, as well as in staff and client records. Updated guidance and information on reporting and enforcement of these new requirements will be issued when this IFC is published.

We specify at §§ 483.80(d)(3)(i) and 483.460(a)(4)(i) that COVID-19 vaccines must be offered when available. If a facility does not have access to the vaccine, we expect the facility to provide, upon request, evidence that efforts have been made to make the vaccine available to its residents or clients, and staff. For example, documentation of communications with the facility medical director, the local health department, or listing of vaccination sites may be used to show efforts to make the vaccine available to residents, clients, and staff. Similar to influenza vaccines, if there is a manufacturing delay, we ask the facility to provide sufficient evidence of such. The infection prevention and control plan is designed to allow for documentation of vaccine efforts. While Pharmacy Partnership clinics are currently the most common avenue for delivering COVID-19 vaccines to LTC facilities, we expect all facilities to be prepared to participate in other distribution programs (possibly through local health departments or traditional pharmacies) as the vaccine continues to become more widely available at a multiplicity of sites.

If an individual resident, client, or staff member requests vaccination against COVID-19, but missed earlier opportunities for any reason (including recent residency or employment,

⁵⁹ Social Security Act. Section 1819(h)(2)(B)(ii). Accessed at https://www.ssa.gov/OP_Home/ssact/title18/1819.htm; and Social Security Act. Section 1919(h)(2)(A)(ii). Accessed at https://www.ssa.gov/OP_Home/ssact/title19/1919.htm. Both accessed on April 28, 2021.

changing health status, overcoming vaccine hesitancy, or any other reason), we expect facility records to show efforts made to acquire a vaccination opportunity for that individual. Although we are not establishing formal timeframes within which vaccination must be arranged for new residents, clients, or staff, we expect LTC facilities and ICFs-IID to support vaccination for these individuals as quickly as practicable. Further, we expect personnel records for facility staff and health records for residents and clients to reflect appropriate administration of any multi-dose vaccine series, including efforts to acquire subsequent doses as necessary.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule before the provisions of the rule are finalized, either as proposed or as amended in response to public comments, and take effect, in accordance with the Administrative Procedure Act (APA) (Pub. L. 79–404), 5 U.S.C. 553, and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Further, 5 U.S.C. 553 requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the Federal Register and a period of not less than 60 days for public comment for rulemaking carrying out the administration of the insurance programs under title XVIII of the Act. Section 1871(b)(2)(C) of the Act and 5 U.S.C. 553 authorize the agency to waive these procedures, however, if the agency for good cause finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Section 553(d) of title 5 of the U.S. Code ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the Federal Register. This 30-day delay in effective date can

be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest. Furthermore, section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest. Finally, the Congressional Review Act (CRA) (Pub. L. 104–121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2).

A. COVID-19 and Populations at Higher Risk

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a “Public Health Emergency of international concern.” On January 31, 2020, pursuant to section 319 of the PHS Act, the Secretary determined that a PHE exists for the United States to aid the nation’s health care community in responding to COVID–19. On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President declared the COVID–19 pandemic a national emergency.

Over 569,000 individuals have lost their lives to COVID-19 in the United States as of April 27, 2021,⁶⁰ including more than 131,000 LTC facility residents, or close to one tenth of the

⁶⁰ <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>

average national LTC facility resident census of 1.4 million.⁶¹ In recognition of the susceptibility of their residents, clients, and staff, LTC facilities and other congregate settings, including ICFs-IID, have been prioritized for vaccination. The data show that COVID-19 cases are declining in LTC facilities concurrently with increasing vaccination among residents and staff, but as noted below, we are concerned that the rate of vaccination in LTC facilities may slow in the absence of regulation and the conclusion of the Pharmacy Partnership program, especially in light of consistent, frequent resident and staff turnover in these facilities and the cold storage chain challenges that exist with two of the three currently available vaccines that make obtaining and providing the vaccine more challenging for small facilities that do not have the necessary storage equipment. Ensuring the health and safety of all Americans, including Medicare and Medicaid beneficiaries, and health care workers is of primary importance. This IFC directly supports that goal by requiring education about and offer of COVID-19 vaccination for LTC facility and ICF-IID residents, clients, and staff. This IFC also requires reporting of COVID-19 vaccination status and use of COVID-19 therapeutics of LTC facility residents and staff, which will provide vital data that CMS, CDC, and other public health entities can use to target our outreach and resources in support of vaccination.

B. Supporting Vaccine Distribution and Uptake

In response to the COVID-19 pandemic, pharmaceutical developers around the world began development of vaccine that would prevent severe illness and death and they have produced several vaccines authorized for use in the United States. Because the first cohort of authorized vaccines require specialized handling, and LTC facility residents have been at higher risk of severe illness from COVID-19, CDC established the Pharmacy Partnership for Long-Term Care (LTC) Program, which has facilitated on-site vaccination of residents and staff at more than 63,000 enrolled nursing homes and assisted living facilities while reducing the burden

⁶¹ LTC Facility deaths are from COVID-19 Nursing Home Data, CMS, Week Ending 3/28/2021, at <https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/>

on facility administrators, clinical leadership, and health departments. At no cost to facilities, the program has provided end-to-end management of the COVID-19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of reporting requirements.

While the Pharmacy Partnerships have had much success in ensuring timely vaccine access to many LTC facility residents and staff, we note that not all such individuals were able to receive vaccine under the program. Internal CDC data show that approximately 2,500 or about 16 percent of CMS-certified SNFs (a subset of LTC facilities enrolled as Medicare providers) that are enrolled in NHSN did not participate in the Pharmacy Partnership program. LTC facility residents are unable to live independently, and generally are unable to access the vaccine without significant assistance from the facility in which they reside or from family members or caregivers. As we currently do not require LTC facilities to report vaccination status within their facility, we have no comprehensive way of knowing whether residents or staff of those facilities have acquired the vaccine through avenues outside the Partnerships. Ensuring that individuals residing in LTC facilities that did not participate in the Pharmacy Partnerships have access to vaccination against COVID-19 is critical so as to expeditiously ensure that residents are protected.

Most LTC facilities participated in the Pharmacy Partnerships but the Partnerships concluded in March 2021. The Pharmacy Partnership program was designed as time-limited effort designed to quickly vaccinate thousands of facility residents per week.

Ending the program without appropriate requirements to ensure facilities continue to seek vaccination opportunities for their residents and staff puts future incoming LTC facility residents and staff at risk. Turnover of both LTC facility residents (admissions and discharges) and staff can be significant. It is difficult to estimate the number of admissions and discharges in LTC facilities as 20 to 25 percent of beds are often reserved for shorter term (weeks to months) rehabilitation stays, while other individuals reside in the facility for years. That said, resident turnover within a year may be significant, possibly up to 40 percent based on internal CMS

estimates. Staff turnover is more easily considered, with some estimates as high as 100 percent for certain facilities within a year,⁶² and if a facility finds itself with a large portion of its community being unvaccinated, all residents and staff may again face a higher risk of infection, similar to the risk levels during the early months of the pandemic. For example, if final Partnership vaccination rates reach even 90 percent (an illustrative example as we do not have final or complete data) of the residents present in the first 3 months of 2021, turnover during the rest of the year may be such that by year-end as few as two-thirds of LTC residents present at some point during the year would have been vaccinated absent a continuing and effective effort.

Turnover rates demonstrate there will be an ongoing need for new resident or staff vaccinations. For example, when the Pharmacy Partnership completes its time commitment, it is likely that it will have seen only about half of the persons who will reside or work in these facilities in 2021. Even if two-thirds of all newly hired staff and newly admitted residents have been vaccinated when they start employment or begin residency, turnover is so high that we estimate an excess of two million persons may still need vaccination in the first year after this rule takes effect. It is critically important that facilities are required to continue to offer vaccination to their residents and staff on an ongoing basis.

Also, we note that some individuals declined the vaccine when it was first offered; approximately 22 percent of LTC facility residents and 62 percent of LTC staff⁶³ initially declined the vaccine, but provisional CDC data suggest that uptake increased over time as the safety and effectiveness of the vaccines has become better understood, and approaches that ameliorate vaccine hesitancy have been identified. For residents and staff who overcome vaccine hesitancy, it is critical to their health and well-being that they are able to get the vaccine when they are ready to receive it.

⁶² <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00957>

⁶³ <https://www.cdc.gov/mmwr/volumes/70/wr/mm7005e2.htm>

All of the concerns that warrant immediate COVID-19 vaccination rulemaking for LTC facilities are also applicable to ICFs-IID. ICF-IID clients continue to be at high risk of serious illness from COVID-19 due to their participation in congregate living and must have ongoing access to the vaccine. While there are no data regarding client and staff turnover rates in ICFs-IID, it is reasonable to assume that staff turnover rates may be as high as those in LTC facilities (see the RIA section of this preamble).

C. Data for COVID-19 Vaccine Reporting: Targeting Resources

Our knowledge of the effects of COVID-19 vaccination in LTC facilities comes from several sources, including reporting by Partnership pharmacies and voluntary reporting by some facilities through NHSN. Direct voluntary vaccination reporting to NHSN by LTC facilities has been very low, with less than 20 percent of facilities reporting on vaccinations through NHSN. Unfortunately, we are unable to examine the effects of accepting or declining participation in the Pharmacy Partnerships because the data are incomplete for LTC facilities and ICFs-IID. Requiring LTC facilities to report on resident and staff vaccination status, in conjunction with the existing COVID-19 testing data, would provide the data necessary to identify the outcomes of Pharmacy Partnership participation and determine vaccine uptake targets. It would also ensure we can identify and address barriers to completing a vaccination series, such as missed or declined second doses.

If this lack of data continues, CDC will have insufficient information upon which to provide support to or revise COVID-19 infection, prevention, and control measures for LTC facilities. While recommendations for routine staff testing could be linked to vaccination rates in each LTC facility (and thus reduce burden on facilities with adequate rates of vaccine coverage), CDC will not have enough data to assess a change in recommendation without full national participation in COVID-19 vaccination reporting by CMS-certified LTC facilities.

Declining infection rates in LTC facilities in early 2021 suggest that vaccination, along with implementation of the full complement of non-pharmaceutical interventions, including

engineering and administrative controls, has reduced the risk of illness and death from COVID-19 for LTC facility residents. Without the reporting mandate, CMS will have no timely way of monitoring whether LTC facilities are complying with the requirement to offer vaccination. Further, such mandatory reporting allows health care agencies and regulators to better evaluate the impact and importance of vaccination. Without a reporting requirement, we will have no way to identify those nursing homes with low vaccination rates so that they can be supported by educational outreach and their residents and staff protected by vaccination.

Unfortunately, we have significant data gaps about the effects of COVID-19 and vaccination rates among ICF-IID clients, with fewer than 80 ICFs-IID voluntarily reporting vaccination data through NHSN. While we recognize that it is impractical to require ICFs-IID to report COVID-19 information to NHSN immediately, we believe that encouraging voluntary reporting is a critical first step in gaining data to help us understand the effects of the pandemic on clients and staff, supporting uptake of COVID-19 vaccine in this community.

D. Moving Forward

For the reasons discussed above, it is critically important that we implement the policies in this IFC as quickly as possible. As the nation continues to address the health impacts of COVID-19, we find good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures. For the same reasons, because we cannot afford sizable delay in effectuating this IFC, we find good cause to waive the 30-day delay in the effective date and, moreover, to make this IFC effective 10 calendar days after this rule is filed for public inspection in the Federal Register.

In this IFC, we follow on policy issued in the September 2, 2020, COVID-19 IFC, which revised regulations to strengthen CMS' ability to enforce compliance with Medicare and Medicaid LTC facility requirements for reporting information related COVID-19 and established a new requirement for LTC facilities for COVID-19 testing of facility residents and

staff. Since the publication of the September IFC, the FDA has issued EUAs for multiple vaccines developed to prevent the spread of SARS-CoV-2.

We anticipate evaluating public input and evolving science before finalizing any requirements.

For this IFC, we believe it would be impractical and contrary to the public interest for us to undertake normal notice and comment procedures and to thereby delay the effective date of this IFC. We find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 553(b)(B), and section 1871(b)(2)(C) of the Act. For those same reasons, we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under the APA, 5 U.S.C. 553(d), section 1871(e)(1)(B)(i) of the Act, and the CRA, 5 U.S.C. 801(a)(3). Therefore, we find there is good cause to waive the delay in effective date pursuant to the APA, 5 U.S.C. 553(d)(3), section 1871(e)(1)(B)(ii) of the Act, and the CRA, 5 U.S.C. 808(2).

We are providing a 60-day public comment period.

IV. Collection of Information (COI) 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 (PRA) 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.

We are soliciting public comments on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

For the estimated costs contained in the analysis below, we used data from the United States Bureau of Labor Statistics to determine the mean hourly wage for the positions used in this analysis. For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in .50 or more, the cost was rounded up to the next dollar. If it was .49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in the chart below.

Table 1: Total Hourly Costs by Position

Position	Mean Hourly Wage	Total Cost
LTC and ICF-IID: RN/IP	\$33.53 ⁶⁴	\$67
LTC: Director of Nursing & ICF-IID: Administrator	\$46.78 ⁶⁵	\$94
LTC: Medical Director	\$ 84.57 ⁶⁶	\$169
LTC: Financial Clerk	\$20.40 ⁶⁷	\$41

A. Long-Term Care Facilities

1. ICRs regarding the development of policies and procedures for § 483.80(d)(3).

At § 483.80(d)(3), we require that LTC facilities develop policies and procedures

⁶⁴ Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 29-1141 Registered Nurses. Accessed at <https://www.bls.gov/oes/current/oes291141.htm>. Accessed on March 18, 2021.

⁶⁵ Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 11-9111 Medical and Health Services Managers. Nursing Care Facilities (Skilled Nursing Facilities). Accessed at <https://www.bls.gov/oes/current/oes119111.htm>. Accessed on February 17, 2021.

⁶⁶ Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 29-1228 Physicians, All Other; and Ophthalmologists, Except Pediatric. General Medical and Surgical Hospitals. Accessed at [https://www.bls.gov/oes/current/oes291228.htm#\(5\)](https://www.bls.gov/oes/current/oes291228.htm#(5)). Accessed on February 17, 2021.

⁶⁷ Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 43-3099 Financial Clerks, All Others. Accessed at <https://www.bls.gov/oes/current/oes433099.htm>. Accessed on March 23, 2021.

to ensure that each resident and staff member is educated about the COVID-19 vaccine. Specifically, before offering the COVID-19 vaccine, all staff members and residents or resident representatives must be provided with education regarding the benefits and risks and potential side effects associated with the vaccine. When the vaccine is available to the facility, each resident and staff member is offered COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized. If an additional dose of the COVID-19 vaccine that was administered, a booster, or any other vaccine needs to be administered, the resident, resident representative, and staff member must be provided with the current information regarding the benefits and risks and potential side effects for that vaccine, before the LTC facility requests consent for administration of that dose. The resident, resident representative, and staff member must be provided the opportunity to refuse the vaccine and change their decision if they decide to take the vaccine. Finally, the resident's medical record includes documentation that indicates, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential risk associated with the COVID-19 vaccine, and that the resident either received the complete COVID-19 vaccine (series or single dose) or did not receive the vaccine due to medical contraindications or refusal. The estimates that follow are largely based on upon our experience with LTC facilities. However, given the uncertainty and rapidly changing nature of the pandemic, we acknowledge that there will likely need to be significant revisions over time as LTC facilities gain experience with these requirements. As previously discussed, we do not have current reporting data on facility compliance with COVID-19 vaccination best practices of the kinds established in this rule. We welcome comments that might improve these estimates.

Based upon our experience with LTC facilities, we believe that some of these facilities have already developed the required policies and procedures. However, since we do not have any reliable method to make an estimate of how many or what percentage of LTC facilities have done so, we will base our estimate for this ICR on all 15,600 LTC facilities needing to develop

new policies and procedures in order to comply with this requirement. These facilities also need to review the policies and procedures to ensure they are up-to-date and make any necessary changes. We believe these activities would be performed by the infection preventionist (IP), director of nursing (DON), and medical director in the first year and the IP in subsequent years as analyzed below.

In the first year, the IP would need to develop the policies and procedures by conducting research and obtaining the necessary information and materials to draft the policies and procedures. The IP would need to work with the medical director and DON to develop and finalize the policies and procedures. For the IP, we estimate that this would require 10 hours initially to develop the policies and procedures, and one hour a month thereafter to review and make changes or updates as needed, for a total of 21 hours (10 hours initially and 1 hour for the 11 months thereafter). According to Table 1 above, the IP's total hourly cost is \$67. Thus, for each LTC facility the burden for the IP would be 21 hours at a cost of \$1,407 (21 hours x \$67). For the IPs in all 15,600 LTC facilities, the burden would be 327,600 hours (21 hours x 15,600 facilities) at an estimated cost of \$21,949,200 ($1,407 \times 15,600$). For subsequent years, the IP would need to review the policies and procedures and make any updates or changes to them. Hence, we estimate that the IP would need 12 hours annually (1 hour x 12 months) at a cost of \$804 (12 hours x \$67). For all LTC facilities, the annual burden would be 187,200 hours (12 x 15,600) at a cost of \$12,542,400 ($15,600 \times \804).

As discussed above, the development and approval of these policies and procedures would also require activities by the medical director and the DON. Both the medical director and the DON would need to have meetings with the IP to discuss the development, evaluation, and approval of the policies and procedures. We estimate that this would require 4 hours for both the medical director and DON. According to Table 1 above, the total hourly cost for a medical director is \$169. For each LTC facility, this would require 4 hours for the medical director during the first year at an estimated cost of \$676 (4 hours x \$169). For the first year, the

burden would be 62,400 (4 x 15,600) at an estimated cost of \$10,545,600 ($\$676 \times 15,600$). For subsequent years, the medical director might need to spend time reviewing or attending meetings to discuss any updates or changes to the policies and procedures; however, that would be a usual and customary business practice. Therefore, these activities for the medical director associated with updating or changing the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

For the DON, we have estimated that the development of policies and procedures would also require 4 hours. According to the chart above, the total hourly cost for the DON is \$94. The burden in the first year for the DON in each LTC facility would be 4 hours at an estimated cost of \$376 (4 hours x \$94). The first year burden would be 62,400 hours (4 x 15,600) at an estimated cost of \$5,865,600 ($\$376 \times 15,600$). For subsequent years, the DON would likely need to spend time reviewing or attending meetings to discuss any updates or changes to the policies and procedures; however, that would be a usual and customary business practice. Therefore, these activities for the DON associated with updating or changing the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

Therefore, for all 15,600 LTC facilities in the first year, the estimated burden for this ICR would be 452,400 hours ($327,600 + 62,400 + 62,400$) at a cost of \$38,360,400 ($\$21,949,200 + \$10,545,600 + \$5,865,600$).

In subsequent years, all 15,600 LTC facilities would have the same burden. The burden for each LTC facility would be 12 hours at an estimated cost of \$804 (12 hours x \$67) for the IP. Hence, for all 15,600 LTC facilities, the burden would be 187,200 (12 x 15,600) at an estimated cost of \$12,542,400 ($\$804 \times 15,600$). The requirements and burden will be submitted to OMB under OMB control number 0938-1363 (Expiration Date 06/30/2022).

2. ICRs regarding LTC Facilities offering the COVID-19 vaccine and obtaining and documenting consent for § 483.80(d)(3)(ii) through (iv).

At § 483.80(d)(3)(i), we require that the facility offer the COVID-19 vaccine to each staff member and resident, when the vaccination is available to the facility, unless the vaccine is medically contraindicated, the resident has already been vaccinated, or the resident or the resident representative has already refused the vaccine. We believe that the LTC facility will offer the vaccine to the staff or resident at the same time the facility provides the education required by § 483.80(d)(3)(ii) and (iii). We note that for LTC facilities contracted with the Pharmacy Partnership, the education and offering of the vaccine are being done by the participating pharmacy. We assume that this cost is about the same as the preceding estimates, so that the first year costs would be about the same whether performed entirely in-house by facility staff or by pharmacy staff who visit the facility.

We note that the LTC facility or the pharmacy would also have to offer the vaccine to the staff member or resident and have that staff member, resident, or resident representative, complete screening for any contraindication or precautions, and for the resident to consent to the vaccination or indicate refusal. These costs are not paperwork burden and are covered in the RIA that follows.

As indicated in the next section, the facility must also ensure that the provision of the education and the resident's decision must be documented in the resident's medical record. If there is a contraindication to the resident having the vaccination, the appropriate documentation must be made in the resident's chart. Documentation regarding a resident's medical care is a usual and customary business practice for a health care provider. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

3. ICRs regarding staff education requirements in § 483.80(d)(3)(ii) through (iv).

At § 483.80(d)(3)(ii), we require that the LTC facility provide all of its staff with education regarding the benefits and potential risks of the COVID-19 vaccine. This would require that the LTC facility develop or choose educational materials for this staff training. We expect that most if not all LTC facilities will use resources developed by other entities as there is

a considerable amount of free information on COVID-19 and vaccines available online. The CMS Nursing Home COVID-19 training program has five modules designed for the frontline clinical staff and ten modules for nursing home management staff (building maintenance staff and other support staff would not take these particular courses). The training is online, at <http://QSEP.cms.gov>, and is summarized in a CMS press release that can be found at <https://www.cms.gov/newsroom/press-releases/cms-releases-nursing-home-covid-19-training-data-urgent-call-action>. In addition, both CDC and FDA provide information on the COVID-19 vaccines online.^{68,69} Finally, we expect that trade publications and other public sources would provide training materials that might complement or substitute for the CMS materials. We believe this educational material would likely be selected by the IP. The IP would need to review the information available on the vaccines, determine what information needs to be presented to staff, and gather that information as appropriate for their facility's staff. We estimate that it would take an average of 4 hours for the IP to accomplish these tasks. Thus, for each LTC facility to meet this requirement would require 4 burden hours at an estimated cost of \$268 (4 x \$67). For all 15,600 LTC facilities, the burden would be 62,400 burden hours (4 x 15,600) at an estimated cost of \$4,180,800 (4 x \$67 x 15,600 facilities).

At § 483.80(d)(3)(iii), we require that LTC facilities provide their residents or resident representatives with education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine. We believe that the education provided to staff and residents or resident representatives will be identical or virtually the same. Hence, we believe that it will not require any additional time or burden to develop the educational materials for the residents and resident representatives. According to § 483.10(g)(3), the facility must ensure that information is provided to each resident in a form and manner the resident can access and

⁶⁸ CDC. Communication Resources for COVID-19 Vaccines. Access at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html>. Updated March 16, 2021. Accessed on March 23, 2021.

⁶⁹ FDA. COVID-19 Vaccines. Access at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>. Updated March 18, 2021. Accessed on March 23, 2021.

understand, including in an alternative format or in a language that the resident can understand. Thus, we expect that this required education would be in a language that the resident or the resident representative understands. Language translations for residents may be available in many facilities from staff, and are virtually always available on demand through services, such as Language Line. LTC facilities are already required to provide information in an alternative format or language the resident or resident representative understands. Any additional costs are minor and are discussed in more detail in the RIA below. At § 483.80(d)(3)(iv), we require that the LTC facility must provide to the staff, resident, or the resident representative, in situation where the vaccination process requires one or more doses of vaccine, up-to-date information regarding the vaccine, including any changes in the benefits or risks and potential side effects associated with the COVID-19 vaccine, before requesting consent for administration of each additional vaccinations. This would require that the IP remains up-to-date on information regarding COVID-19 vaccines and ensures the information provided to the resident and the resident representative before requesting consent for the administration of each additional dose of vaccine includes current information on the benefits and potential risks associated with the vaccine. We believe that this activity would require that the IP routinely review CDC and FDA websites for updates and make any necessary changes to the education materials used by the LTC facility. We estimate that this would require 6 hours of an IP's time annually. Thus, for each LTC facility to meet this requirement would require 6 burden hours at an estimated cost of \$402 (6 x \$67). For all LTC facilities, the annual burden would be 93,600 (6 hours x 15,600) hours at an estimated cost of \$6,271,200 (\$402 x 15,600). We estimate that the burden to the LTC facilities will be similar in subsequent years due to the large turnover in these facilities. The requirements and burden will be submitted to OMB under OMB control number 0938-1363 (Expiration Date 6/30/2022).

4. ICRs regarding the documentation requirements in § 483.80(d)(3)(vi) and (vii)

At § 483.80(d)(3)(vi), we require that the facility ensure that the resident's medical record is documented with, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential risks associated with the COVID-19 vaccine and that the resident either received the COVID-19 vaccine, did not receive the vaccine due to medical contraindications, or refused the vaccine. This would require that a health care provider, probably a licensed nurse, would retrieve the resident's medical record and document that the education was provided and whether the resident or resident representative had consented or refused the vaccine or whether the vaccine was contraindicated. We estimate that this would require only a few seconds per resident, but estimate no costs as maintaining a medical record is a usual and customary business practice. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

As discussed above in section II.A. of this rule, the LTC facility would also be required to document that the required education was provided to its staff that must include the benefits and potential risks associated with of the COVID-19 vaccine as set forth in § 483.80(d)(3)(ii). Section 483.80(d)(3)(vii) sets forth that the LTC facility must maintain documentation on its staff regarding the education provided; that the staff person was offered the COVID-19 vaccine or information on obtaining the vaccine, and his or her vaccine status and related information indicated by the NSHN. This would require that a staff person document the required information in the staff person's record. We estimate that this would require one half-hour per month per facility. According to Table 1 above, the total hourly cost of a financial clerk is \$41. For each LTC facility, we estimate that the burden for this activity would be 6 hours at an estimated cost of \$246 ($\$41 \times 12 \times .5$). For all LTC facilities, this would require 93,600 ($12 \times .5 \times 15,600$) burden hours at an estimated cost of \$3,837,600 ($\$41 \times 12 \times .5 \times 15,600$). We estimate that the burden to the LTC facilities will be similar in subsequent years due to the large turnover in these facilities. The requirements and burden will be submitted to OMB under OMB control number 0938-1363.

5. ICRs regarding the reporting requirements to CMS and CDC (NSHN) § 483.80(g)(1)(viii) and (ix)

Section 483.80(g)(1)(viii) requires LTC facilities to electronically report information about COVID-19 in a standardized format to the NHSN about the COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, COVID-19 vaccination adverse events. The LTC facility must also report the therapeutics administered to residents for treatment of COVID-19.

We believe the IP would do this weekly reporting to the NHSN, because this reporting would require information on the therapeutics that were administered to resident for treatment of COVID-19. We believe this additional reporting would require about 30 minutes or .5 hour each week for the IP. Thus, for each LTC facility, this burden would be 26 hours (.5 x 52 weeks) at an estimated cost of \$1,742 (\$67 x 26) annually. For all LTC facilities, the burden would be 405,600 hours (26 x 15,600) at an estimated cost of \$27,175,200 (\$1,742 x 15,600) annually.

Thus, the total annual burden for all LTC facilities to comply with the requirements in this IFC in the first year is 1,107,600 (452,400 + 62,400 + 93,600 + 93,600 + 405,600) hours at an estimated cost of \$79,825,200 (\$38,360,400 + \$4,180,800 + \$6,271,200 + \$3,837,600 + \$27,175,200). In subsequent years, the burden would be 780,000 hours (187,200 + 93,600 + 93,600 + 405,600) at an estimated cost of \$49,826,400 (\$12,542,400 + \$6,271,200 + \$3,837,600 + \$27,175,200). See Table 2 below. The requirements and burden will be submitted to OMB under OMB control number 0938-1363.

Table 2: Total Cost for COI Requirements for all LTC Facilities

COI Requirements	First Year		Subsequent Years	
	Burden Hours	Costs	Burden Hours	Costs
§483.80(d)(3) Developing Policies and Procedures	452,400	\$38,360,400	187,200	\$12,542,400

§483.80(d)(3)(ii) & (iii) Developing education materials for staff members and residents and residents' Representatives	62,400	\$4,180,800	N/A	N/A
§483.80(d)(3)(iv) Keeping vaccine information up-to-date and Making necessary changes	93,600	\$6,271,200	93,600	\$6,271,200
§483.80(d)(3)(vi) and (vii) Documentation requirements	93,600	\$3,837,600	93,600	\$3,837,600
§483.83(d)(3)(viii) and (ix) NHSN Reporting	405,600	\$27,175,200	405,600	\$27,175,200
Totals	1,107,600	\$ 79,825,200	780,000	\$49,826,400

B. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-IIDs)

1. ICRs regarding the development of policies and procedures for § 483.460(a)(4).

At new § 483.460(a)(4), we require that ICFs-IID develop policies and procedures to ensure that each client or client's representative and staff member is educated about the COVID-19 vaccine. Specifically, before offering the COVID-19 vaccine, all staff members and clients or client representatives must be provided with education regarding the benefits and risks and potential side effects associated with the vaccine. When the vaccine is available to the facility, each client and staff member is offered COVID-19 vaccine unless the immunization is medically contraindicated or the client or staff member has already been immunized. If an additional dose of the COVID-19 vaccine that was administered, a booster, or any other vaccine needs to be administered, the client, client representative, and staff member must be provided with the current information regarding the benefits and risks and potential side effects for that vaccine, before the ICF-IID requests consent for administration of that dose. The client, client's representative, and staff member must be provided the opportunity to refuse the vaccine and change their decision if they decide to take the vaccine. Finally, the client's medical record must include documentation that indicates, at a minimum, that the client or client's representative was provided education regarding the benefits and risks and potential side effects of the COVID-19

vaccine and each dose of the COVID-19 vaccine administered to the client or if the client did not receive a dose due to medical contraindications or refusal.

We believe that developing these policies and procedures would require a RN to gather the necessary information and materials and draft the policies and procedures. The facility must also ensure that these materials are in an accessible format for the client and his or her representative. It must be in a language that they understand and in a format that is accessible to them, such as Braille or large print for a person who is visually-impaired or in American Sign Language for a person who is hearing-impaired. The RN would need to work with an ICF-IID administrator who would likely provide input and guidance in developing the policies and procedures and would need to approve them before they go before the governing body for approval. For the RN, we estimate that this would require 5 hours initially, and 30 minutes or .5 hour a month thereafter to review for updated information to determine if any changes need to be made to the policies or procedures and then make any necessary changes. According to Table 1 above, the total hourly cost for an RN is \$67. We estimate that for each ICF-IID, the burden would be 10.5 hours (5 hours initially + 5.5 (11 x .5)) for the RN during the first year at an estimated cost of \$704 ($\67×10.5 hours). Assuming 5,772 ICFs-IID, for the first year the burden for all facilities would be 60,606 burden hours ($10.5 \times 5,772$ facilities) at an estimated cost of \$4,060,602 ($10.5 \times \$67 \times 5,772$). In subsequent years, the burden for this activity for each facility would be 6 hours (.5 hour x 12 months) at an estimated cost of \$402 ($6 \times \67). In subsequent years the burden for all facilities would be 34,632 ($6 \times 5,772$) burden hours at an estimated cost of \$2,320,344 ($6 \times \$67 \times 5,772$).

For the ICF-IID administrator, we believe it would require 3 hours to work with the RN in developing the policies and procedures and give final approval before taking the policies and procedures to the governing body for approval. We believe that the administrator would likely make a salary similar to that of a manager in the LTC setting, like that for the DON salary as discussed above. Therefore, we estimate that an ICF-IID administrator's hourly mean salary is

about \$94. Thus, for each ICF-IID, the burden hours for the administrator would be 3 hours at an estimated cost of \$282 (3 x \$94). For all 5,772 ICFs-IID, the total burden for the administrator would be 17,316 hours (3 x 5,772 facilities) at an estimated cost of \$1,627,704 (\$282 x 5,772 facilities).

As discussed above, the ICF-IID administrator would need to obtain approval from the ICF-IID's governing board for the policies and procedures. Since the review and approval of policies and procedures should be encompassed within the governing board's responsibilities, this activity would be usual and customary and exempt from the information collection estimate. In addition, in subsequent years the ICF-IID administrator might need to spend time reviewing or attending a meeting to discuss any updates to the policies and procedures; however, that would also be a usual and customary business practice. Therefore, this activity is exempt from the PRA in accordance to 5 CFR 1320.3(b)(2).

Therefore, for all ICFs-IID, the total annual burden in the first year for the required policies and procedures would be 77,922 burden hours (60,606 + 17,316) at an estimated cost of \$5,688,306 (\$4,060,602 + \$1,627,704). In subsequent years, the burden would only be for the RN and it would be 34,632 burden hours at an estimated cost of \$2,320,344. The requirements and burden will be submitted to OMB under OMB control number 0938-New.

2. ICRs regarding the ICFs-IID offering the vaccine and obtaining and documenting consent in § 483.460(a)(4)(i).

At new § 483.460(a)(4)(i), we require that the ICF-IID offer the COVID-19 vaccine to each staff member and client, when the vaccination is available to the facility, unless the vaccine is medically contraindicated, the client has already been vaccinated, or the client or the client representative has already refused the vaccine. We believe that the ICF-IID will offer the vaccine to the client or the client representative at the same time the facility provides the education required by new § 483.460(a)(4)(ii). This activity would require that the ICF-IID offer the vaccine to the staff member or resident and have that staff member, client, or client

representative complete screening for any contraindication or precautions, and for the client or client representative consent to the vaccination or indicated refusal. This is not a paperwork burden and are covered in the RIA that follows.

3. ICRs regarding the education requirements in § 483.460(a)(4)(ii), (iii), and (iv).

At new § 483.460(a)(4)(ii), we require that the ICF-IID provide all of its staff with education regarding the benefits and potential risks associated with of the COVID-19 vaccine. New § 483.460(a)(4)(iii) requires that the ICF-IIF to provide each client or the client's representative education regarding the benefits and risks and potential side effects associated with the vaccine. In addition, new § 483.460(a)(4)(iv) requires that the ICF-IID, in situations where there is an additional dose of the COVID-19 vaccine that was administered, a booster, or any other vaccine needs to be administered, must provide the client, client's representative, and staff member with the current information regarding the benefits and risks and potential side effects for that vaccine, before the facility requests consent for administration of that dose. We believe that all of the education provided by the ICF-IID to the client, client's representative and the staff would be virtually identical.

For the initial education, the ICF-IID would be required to develop educational materials by reviewing available resources on COVID-19 vaccines. We expect that most if not all ICFs-IID will use resources developed by other entities as there is a considerable amount of free information on COVID-19 and its vaccines available online. For example, CDC and FDA provide information on the COVID-19 vaccines online.^{70,71} Finally, we expect that trade publications and other public sources would provide training materials. We believe this educational material would likely be selected by the RN. The RN would need to review the information available on the vaccines, determine what information needs to be presented to the client, client's representative and staff members, and gather that information as appropriate. An

⁷⁰ See FN#71.

⁷¹ See FN#72.

ICF-IID administrator would likely work with the RN and need to approve the final educational material. We estimate that it would initially require 7 hours and thereafter 6 hours annually to review for updates and make those changes to the educational materials for a total of 13 hours for the RN to accomplish these tasks in the first year. Thus, for each ICF-IID, the burden for the RN would require 13 burden hours at an estimated cost of \$871 (13 x \$67). For all 5,772 ICFs-IID so the burden for all facilities would be 75,036 burden hours (13 hours X 5,772 facilities) at an estimated cost of \$5,027,412 (5,772 hours x \$871).

For the education required in subsequent years, the RN would need to ensure that the information regarding COVID-19 vaccines that is provided to the staff, client and the client's representative before requesting consent for each additional dose of the vaccine is current. We believe that this activity would require the RN to routinely review CDC and FDA websites for updates and make any necessary changes to the education materials used by the ICF-IID. We estimate that this would require 6 hours of an IP's time annually. Thus, for each ICF-IID to meet this requirement would require 6 burden hours at an estimated cost of \$402 (\$67 x 6 hours). For all ICFs-IID, meeting this requirement would require 34,632 burden hours (6 hours x 5,772 facilities) at an estimated cost of \$2,320,344 (5,772 x \$402). The requirements and burden will be submitted to OMB under OMB control number 0938-New.

4. ICRs regarding the documentation requirements in § 483.460(a)(4)(vi) and (f).

At new § 483.460(a)(4)(vi), the ICF-IID must 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 potential risks associated with the COVID-19 vaccine and that the resident either received the COVID-19 vaccine or did not receive the vaccine due to medical contraindications, or refused the vaccine. This would require that the RN to retrieve the client's medical record and document the required information. We estimate that this would require only a few seconds per client but estimate no costs as maintaining a medical record is a usual and

customary business practice. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

At new § 483.460(f), the ICF-IID is required to, at a minimum, document that their staff were provided education regarding the benefits and potential risks associated with the COVID-19 vaccine and that each staff member was offered the vaccine or was provided information on how to obtain it. This would require that a staff person document that these tasks were accomplished. We estimate that this would require one quarter or 0.25 hour per month per facility and that this task would be performed by administrative staff, probably a financial clerk. According to Table 1 above, the total hourly cost for a financial clerk of \$41. For each ICF-IID it would require 3 hours annually (0.25 x 12) at an estimated cost of \$123 (\$41 x 3 hours). For all ICFs-IID, the documentation requirements in this IFC this would require 17,316 burden hours (3 hours x 5,772 facilities) at an estimated cost of \$709,956 annually (17,316 hours x \$123).

In total, we estimate that information collection burden for all ICFs-IID would be about 170,274 hours and \$11,425,674 in the first year and 86,580 hours and \$5,350,644 in subsequent years.

Table 3: Total Burden for COI Requirements for all ICFs-IID

COI Requirement	First Year		Subsequent Years	
	Burden Hours	Costs	Burden Hours	Costs
§483.460(a)(4) Developing the policies and procedures	77,922	\$5,688,306	34,632	\$2,320,344
§483.460(a)(4)(ii), (iii), and (iv) Education requirements	75,036	\$5,027,412	34,632	\$2,320,344
§483.460(a)(4)(v) and (f) Documentation requirements	17,316	\$709,956	17,316	\$709,956
Totals	170,274	\$11,425,674	86,580	\$5,350,644

The total burden estimate for the information collection burden in both LTC facilities and ICFs-IID in the first year is 1,277,874 hours (1,107,600 +170,274) at an estimated cost of \$91,250,874 (\$79,825,200+ \$11,425,674) and in subsequent years the burden is estimated at 866,580 hours (780,000 + 86,580) at a cost of \$55,177,044 (\$49,826,400 + \$5,350,644). The requirements and burden will be submitted to OMB under OMB control number 0938-1363 for the LTC facilities and 0938-New for the ICFs-IID.

Table 4: Total COI Burden for LTC Facilities and ICFs-IID in this IFC

Type of Facility	First Year		Subsequent Years	
	Burden Hours	Costs	Burden Hours	Costs
LTC Facility	1,107,600	\$79,825,200	780,000	\$49,826,400
ICFs-IID	170,274	\$11,425,674	86,580	\$5,350,644
Totals	1,277,874	\$91,250,874	866,580	\$55,177,044

If you comment on this information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the ADDRESSES section of this interim final rule.

Comments must be received on/by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

The COVID-19 pandemic has precipitated the greatest economic crisis since the Great Depression, and one of the greatest health crises since the 1918 Influenza pandemic. Of the approximately 540,000 Americans estimated to have died from COVID-19 through March 2021,⁷² over one-third are estimated to have died during or after a nursing home stay.⁷³ The development and large-scale utilization of vaccines to prevent COVID-19 cases and have the potential to end future COVID-19-related nursing home deaths. But this huge achievement depends critically on success in vaccination of nursing home residents and staff. This interim final rule will close a gap in current regulations, which are silent on the subject of vaccination to prevent COVID-19.

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), 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). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially

⁷² <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>

⁷³ For updated data, see CDC daily updates of total deaths at <https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm>, and the Kaiser Family Foundation weekly updates on nursing home deaths at <https://www.kff.org/coronavirus-covid-19/issue-brief/state-covid-19-data-and-policy-actions/>, among other sources.

affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that, taken together with COI section and other sections of the preamble, presents to the best of our ability the costs and benefits of the rulemaking.

This RIA focuses on the overall costs and benefits of the rule, taking into account vaccination progress to date or anticipated over the next year that is not due to this rule, and estimating the likely additional effects of this rule. We analyze both the costs of the required actions and the payment of those costs. As intended under these requirements, this RIA’s estimates cover only those costs and benefits that are likely to be the effects of this rule. In the case of the COVID-19 PHE, there is rapid and massive improvement through vaccination, social distancing, treatment, and other efforts already underway, and this rule would have relatively small effects compared to these other efforts, past, present, and future. There are also a number of unknowns that may affect current progress or this rule or both. There are many unknowns (for example, whether vaccine protection lasts only one year rather than 3 years or more, and the possibility of variants that reduce the effectiveness of currently approved vaccines) and we cannot estimate the effects of each of the possible interactions among them, but throughout the

analysis we point out some of the most important assumptions we have made and the possible effects of alternatives to those assumptions.

This rule presents additional difficulties in estimating both costs and benefits due primarily to the fact that an unknown but significant fraction of current LTC staff and residents have already received an explanation of the benefits of vaccination to persons who are elderly or high risk from specific health conditions or both, and the rarely serious risks associated with vaccination (for example, the statistically negligible risk of severe allergic reactions to the vaccine). For a statistically average LTC resident, the average pre-COVID life expectancy if death occurs while in the facility is likely to be on the order of 3 years or fewer but taking into account those who recover and leave the facility and those enrolled for skilled nursing services we estimate overall life expectancies to be about 5 years.⁷⁴ We also estimate that vaccination reduces the chance of infection by about 95 percent, and the risk of death from the virus to a fraction of 1 percent.⁷⁵ (In Israel, of the first 2.9 million people vaccinated with two doses there were only about 50 infections involving severe conditions resulting from the virus after the 14th day and of these so few deaths that they were not reported in statistical summaries. These data also show that vaccine effectiveness rates are very high for both older and younger recipients. Of those receiving the second vaccine dose, after the 14th day 46 people over the age of 60 became infected and had a severe case, compared to 6 people under the age of 60. Two million nine hundred thousand (2.9 million) people received a second dose; therefore both rates are near zero.)⁷⁶

⁷⁴ At age 80, the average life expectancy of a male is about 8 years and of females about 10 years, or an overall average of about 9 years. Long-term care nursing home residents, however, have shorter life expectancies because they have severe health problems or would not have been admitted to a facility. For those who die while in a facility the average life expectancy is about two years. But some recover and leave so we have used five years as a reference point. See discussion at David B. Reuben, “Medical Care for the Final Years of Life: “When you’re 83, It’s not going to be 20 years,”” JAMA, Dec. 23, 2009, 2686-2694.

⁷⁵ For patients in skilled nursing facilities, average length of stay is less than a month. Hence, turnover is far higher.

⁷⁶ See Dvir Aran, Estimating real-world COVID-19 vaccine effectiveness in Israel using aggregated counts, medRxiv, February 28, 2021, at <https://www.medrxiv.org/content/10.1101/2021.02.05.21251139v3.full.pdf> and Noa Dagan et al, “BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting,” The New England Journal of Medicine, 2/24/2021, at <https://www.nejm.org/doi/full/10.1056/NEJMoa2101765>.

C. Anticipated Costs of the Interim Final Rule

The previously calculated information collection costs of this rule are one of three major categories of cost. The second large cluster of costs are for the required resident, client, and staff education. In addition, we are requiring facilities to offer COVID-19 vaccines to residents, clients, and staff.

As documented subsequently in this analysis and in a research report on this issue, about 1.5 million individuals work in nursing facilities at any one time.⁷⁷ These individuals are at high risk both to become infected with COVID-19 and to transmit the SARS-CoV-2 virus to residents or visitors. Far more than most occupations, nursing home care requires sustained close contact with multiple persons on a daily basis.

In Table 5, we present estimates of total numbers of individuals in the categories regulated under this rule, distinguishing among long-term and shorter-term nursing facility residents, residents and staff, and numbers at the beginning of a year and at any one time during the year, versus the much higher numbers when turnover is taken into account. In this table we assume that the number departing each year is the same as the number entering each year, which is a reasonable approximation to changes in just a few years, but do not take account of the aging of the population over time.

These figures are approximations, because none of the data that is routinely collected and published on resident populations or staff counts focus on numbers of individuals residing or working in the facility during the course of a year or over time. Depending on the average length of stay (that is, turnover) in different facilities, an average population at any one time of, for example, 100 persons would be consistent with radically different numbers of individuals, such as 112 individuals in one facility if one person left each month and was replaced by another

⁷⁷ Kaiser Family Foundation, COVID-19 and Workers at Risk: Examining the Long-Term Care Workforce, April 23, 2020, at <https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-and-workers-at-risk-examining-the-long-term-care-workforce/>

person, compared to 365 if one person left each day and was replaced that same day by another person.

In Table 5, we assume it is likely that about 80 or 90 percent of LTC facility residents at the beginning of the year, and 60 or 70 percent of the LTC facility staff at the beginning of the year, were vaccinated by the end of March, due mainly to the efforts of the Partnership. But there are many new persons in each category during the first three months (one fourth of the annual number shown in the second column) and likely fewer of these will have been vaccinated elsewhere. Hence, we assume that the percent of persons who were vaccinated by the end of March is only 70 percent of long-term care residents, 40 percent of skilled nursing care residents, and 60 percent of the LTC facility staff serving both types of residents. The estimated numbers for ICFs-IID are lower because few residents or staff were eligible for vaccination from any source other than the Partnership in the first three months of the year. The estimated numbers of ICF-IID residents and staff, and turnover rates, are particularly rough estimates since there are no published sources that we have found that contain such estimates. We assume that staff turnover is about as high as in LTC facilities, but that resident turnover is considerably lower since resident mortality is not a major factor.

The estimate that 53 percent of these LTC facility and ICF-IID populations as of the end of March were actually vaccinated is simply a weighted average of these numbers. The second and third sections of Table 5 show how these numbers are split between residents and staff, and LTC facilities and ICFs-IID, respectively. This table estimates that during the first year after the issuance of this regulation, as many people will be candidates for vaccination in these facilities as during the first three months of calendar year 2021 (see last column).

Table 5: Estimates of Number and Vaccination Status of Residents and Staff (thousands)

	Begin- ning of Year 2021*	New During 2021	Total for 2021	Percent Vaccin- ated by March 31	Number Vaccin- ated by March 31	Remain- ing Vaccin- ation Candi- dates 2021	New Candi- dates 1st Quar- ter 2022	Total First Year Candi- dates **
Long-Term Care Residents	1,200	400	1,600	70%	1,120	480	100	580
Skilled Nursing Care Residents	200	2,100	2,300	40%	920	1,380	525	1,905
LTC Facility Staff	950	760	1,710	60%	1,026	684	190	874
ICF-IID Residents	100	20	120	20%	24	96	5	101
ICF-IID Staff	75	60	135	20%	27	108	15	123
Total Persons	2,525	3,340	5,865	53%	3,117	2,748	835	3,583

Residents Total	1,500	2,520	4,020	51%	2,064	1,956	630	2,586
Staff Total	1,025	820	1,845	57%	1,053	792	205	997
Total Persons	2,525	3,340	5,865	53%	3,117	2,748	835	3,583

LTC Facility Total	2,350	3,260	5,610	55%	3,066	2,544	815	3,359
ICF-IID Total	175	80	255	20%	51	204	20	224
Total Persons	2,525	3,340	5,865	53%	3,117	2,748	835	3,583

* Beginning of Year is roughly identical to average for year when population is stable.

** Estimated number potentially needing vaccination in the first full year after March 31st.

As presented in the third numeric column of Table 5, the total number of individuals either residing or working in all of these different facilities over the course of a year is about 5.9 million persons, which is more than twice the annual average number of residents or staff shown in the first numeric column. A new study, using data from detailed payroll records, found that median turnover rates for all nurse staff are approximately 90 percent a year.⁷⁸ Due to these high turnover rates, LTC facilities will require significantly more resident or staff vaccines compared to the total number of residents and staff in the facility at the beginning of the year. For example, when the Pharmacy Partnership completed its time commitment in LTC facilities, it probably had seen only about half of the persons who will reside or work in these facilities in

⁷⁸ Ashvin Gandhi et al., “High Nursing Staff Turnover In Nursing Homes Offers Important Quality Information,” Health Affairs, March 2021, pages 384-391.

2021. Of course, most of these persons will have been vaccinated through other means when they enter the facilities during the remainder of 2021. That said, it is likely that there will be over one million residents and staff during the first year after this rule is published who will need vaccination. Much of the immediate need for LTC resident and staff education has already been accomplished through the Pharmacy Partnership for Long-Term Care Program. Even after the end of this program, remaining unvaccinated residents and staff will benefit from additional education, especially as additional information about vaccine safety and effectiveness is available. Some resident education can take place in group settings and some education will take place on a one-to-one level. What works best will depend on the circumstance of the resident and the best method for conveying the information and answering questions. Staff can use opportunities during normal day-to-day activities to educate the residents and their representatives (if they are present) on the immunization opportunities through the facility or its partners. Staff education, using CDC or FDA materials, can also take place in various formats and ways. Individualized counseling, resident meetings, staff meetings, posters, bulletin boards, and e-newsletters are all approaches that can be used to provide education. Informal education may also occur as staff go about their daily duties, and some who have been vaccinated may promote vaccination to others. Facilities may find that reward techniques, among other strategies, may help. In particular, the value of immunization as a crucial component of keeping residents healthy and well is already conveyed to staff in regard to influenza and pneumococcal vaccines. The COVID-19 vaccine education will build upon that knowledge.

The techniques for education and shared decision-making, where appropriate, are so numerous and varied that there is no simple way to estimate likely costs. Staff and resident hesitancy may and likely will change over time as the benefits of vaccination become clear to increasing numbers of participants in congregate settings. For purposes of estimation, we assume that, on average, 30 minutes of staff time will be devoted to education of each unvaccinated resident, resident representative, or staff person, at the same average hourly cost of

\$67.06 estimated for RNs in the Information Collection analysis. As for the recipients of such education, we assume that about three-fourths of them are residents, and one-fourth staff. We have little data on resident income but know that for most, Social Security or Supplemental Security Income are their principal sources of income.⁷⁹ For estimating purposes, we assume that their time is worth about \$10.02 an hour (median income of older adults without earnings is \$20,440 annually.⁸⁰ Since residents are rarely in the labor market while in the facility, this base income has not been adjusted for fringe benefits or employer expenses. For staff, we estimate hourly costs of \$27.38 based on BLS data for healthcare support occupations (median of \$13.69, doubled to account for fringe benefits and overhead).

We note that very little of this cost is likely to involve translation of documents, simply because very few documents are involved, and electronic and other assistance methods are so widespread. The vaccine information Fact Sheet required by FDA to be made available is already translated by FDA into the eight most common non-English languages in use in the United States and is downloadable online. (For the Moderna vaccine, for example, see <https://www.modernatx.com/covid19vaccine-eua/providers/language-resources>.) LanguageLine or similar services are always available on call if needed for an oral explanation of a written document to someone who does not speak English. Many computer and phone applications (“Apps”) providing oral translations are available to assist those with language or vision problems, and hearing problems create no document translation requirements if a document in the reading language of that resident is available.⁸¹

If we assume that 20 percent of residents and clients in LTC facilities and ICFs-IID decline vaccination, taking account of both those offered and declining the vaccine before this rule takes effect and those offered it again in the first year, 930,000 additional vaccination

⁷⁹ Only about 13% have private sources of payment. See Jose Ness et al, “Demographics and Payment Characteristics of Nursing Home Residents in the United States: A 23-Year Trend,” *Journal of Gerontology: MEDICAL SCIENCES*, 2004, Vol. 59A, No. 11, pp. 1213-1217.

⁸⁰ Average income from Federal Reserve of St. Louis at <https://fred.stlouisfed.org/series/MEPAINUSA672N>.

⁸¹ Examples of translation Apps include Google Translate, iTranslate Voice 3, SayHi, TextGrabber, BrailleTranslator, and many more.

counseling and education efforts would be made to residents (4,020,000 including 630,000 in the first quarter of 2022 for a total of 4,655,000 total individual residents x .2). This figure implicitly assumes that a much higher take-up rate was achieved during the first three months of 2021, likely about 80 to 90 percent of all those residents reached by Pharmacy Partners and other early vaccination efforts, and that there will be more and more varied effort needed for the remainder, most of whom presumably declined the initial offer. It also assumes that only about half of year-end residents will have been vaccinated when this rule is issued even though most residents at the beginning of the year will have been vaccinated. Hence, there will be about 517,000 residents needing vaccine education and offers needed to be made in the first full year (20 percent of rightmost Residents Total column of Table 5).

For education of staff, we make similar assumptions, except that early and anecdotal evidence suggests that a third or more are declining vaccination.⁸² This means that about an additional 332,000 (one-third of 997,000) vaccination counseling and education efforts will need to be made to staff, including new hires, in the remainder of 2021 and the first quarter of 2022.

Taken together, these estimates for both residents and staff suggest that total counseling and education efforts would be made for perhaps 849,000 persons after the rule is issued, two-thirds residents and one-third staff. Some of those offers would be accepted and some declined (these figures do not include offers made to persons already vaccinated but do include those newly admitted to or hired by these facilities). Total cost of the educational efforts themselves would be approximately \$28,442,000 (849,000 persons x .5 hours x \$67 hourly cost). Cost of resident time to participate would be an additional \$2,449,000 (849,000 persons x .667 x .5 hours x \$8.65 hourly cost) and of staff time to participate an additional \$1,631,000 (849,000 persons x .333 x .5 hours x \$27.38 hourly costs). Second- and third-year totals would be lower, perhaps about three-fourths as much, taking into account both fewer remaining unvaccinated

⁸² The Kaiser Family Foundation estimates as of February 22 that to date 37 percent of all health care workers (not specific to LTC workers) have declined vaccination or decided to wait and see. See <https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor/>

needing these efforts, and a sensible reduction in efforts aimed at persons who refuse to consider vaccination. Hence, total cost of these educational efforts to both educators and recipients would be a total of \$35,220,000 in the first year and \$26,415,000 in the second and third years.

The third major cost component is the vaccination, including both administration and the vaccine itself. We estimate that the average cost of a vaccination is what the Government pays under Medicare: $\$20 \times 2 = \40 for two doses of a vaccine, and $\$20 \times 2$ for vaccine administration of two doses, for a total of \$80 per resident. This estimate is made for simplicity, ignoring newer and one-dose vaccines, since the great majority of recipients are Medicare beneficiaries and we have no data yet on likely use of newer vaccines.⁸³ Assuming that the efforts to educate residents, clients, and staff succeed in raising the vaccinated percentage by 5 percent points over the course of the first year, calculated from the 70 percent (staff) to 80 percent (residents and clients) baseline likely to be achieved before this rule takes effect, total vaccination costs across these target groups resulting from this rule would be \$23,460,000 ($\$80 \times .05 \times 5,865,000$).

Finally, there is a cost category related to expenses not estimated as information collection costs because they meet an exception in the PRA for requirements that would be handled through “usual and customary” business practices. These exceptions are all discussed briefly in the ICR section of this preamble. Most of their costs are related mainly to recording in patient or personnel records for each resident and staff person that vaccine education, vaccine decision, and vaccinations for those accepting vaccination have all taken place. While there are large numbers of such record notations to be made, we estimate that they take only a few seconds per record. We have estimated that the added cost of these record-keeping functions as likely to be about 5 percent of all Information Collection costs.

⁸³ Vaccine and vaccination costs are generally paid by the Federal Government. What the Government pays varies from vaccine to vaccine, by when purchased and in what quantities, and varies by payer or provider. \$40 per dose is a rough estimate based on experience to date. As is the case for all drugs, cost estimates also vary depending on research and development costs as well as manufacturing cost. These estimates do not reflect use of the new Johnson & Johnson/Janssen one-dose vaccine. See the Healthline article at <https://www.healthline.com/health-news/how-much-will-it-cost-to-get-a-covid-19-vaccine>

All these aggregate costs can be converted to per person numbers since it is individual persons who are vaccinated. Dividing the estimated first year costs by an estimated 5.380 million people (4.02 million residents and 1.36 million workers) gives an average per resident or employee cost of \$27.12 in the first year (159,056,000 divided by 5,865,000).

Another way to summarize these numbers is in terms of average cost per person newly vaccinated. Making the same assumption that about 5 percent of total persons (and 10 percent of those unvaccinated) would be newly vaccinated as a result of this rule, cost per person would be \$542(\$27.12 divided by .05). Table 6 summarizes the overall cost estimates.

Table 6: Estimate of Total Costs

Cost Category	Costs in First Year	Costs in Succeeding Years
Developing NF Policies & Procedures	\$38,360,000	\$12,542,000
Developing Education Materials for Residents and Staff	\$4,181,000	NA
Keeping Vaccine Information Up-to-Date	\$6,271,000	\$6,271,000
Documentation Requirements	\$3,838,000	\$3,838,000
NHSN Reporting to CDC and CMS	\$27,175,000	\$27,175,000
Subtotal, NF Information Collection	\$79,825,000	\$49,826,000
ICF-IID Information Collection	\$11,426,000	\$5,351,000
Subtotal Information Collection	\$91,251,000	\$55,177,000
Educating Residents & Staff*	\$35,220,000	\$26,415,000
Providing Vaccine to Residents and Staff**	\$23,460,000	\$17,595,000
Keeping Records of the Above Activities	\$9,125,000	\$5,518,000
Total Costs	\$159,056,000	\$104,705,000

* These costs assume only unvaccinated are educated about vaccination.

** These costs assume about 5 percent of total persons accept the vaccine offer (over half already vaccinated).

While these estimates give the appearance of precision since they present costs to the nearest thousand dollars, this is simply the result of calculations based on numerical assumptions. There are major uncertainties in these estimates. One obvious example is whether vaccine efficacy will last more than the six months proven to date.⁸⁴ Presumably, re-vaccination each year could maintain a high level of protection if vaccine protection wore off in a year. Re-vaccination or use of new and improved vaccines would likely maintain the effectiveness of vaccination for residents and staff. But the estimated costs of this rule would change in the table column for succeeding years to a level roughly equal to the first year estimate even if re-vaccinations were to be necessary. For purposes of displaying the known second (and succeeding) year effects assuming no major changes in vaccine effectiveness, we have included in Table 5 (and the tables covering information collection costs) the predictable changes in second year cost estimates.

D. Anticipated Benefits of the Interim Final Rule

There will be over 5 million residents, clients, and staff each year in the LTC facilities and ICFs-IID covered by this rule. In our analysis of first-year benefits of this rule we focus on prevention of death among residents of LTC facilities and ICFs-IID, as well as on progress in reducing disease severity. We also focus only on benefits to the candidates for vaccination covered by this rule, not on possible benefits to family members, caregivers, or other persons who they might subsequently infect if not vaccinated.⁸⁵ Reductions in resident, client, and staff mortality are benefits for which techniques exist (though with some uncertainty) to express

⁸⁴ For a discussion of this issue, see Sumathi Reddy, “How Long To Covid-19 Vaccines Protect You?”, The Wall Street Journal, April 13, 2021, at <https://www.wsj.com/articles/how-long-do-covid-19-vaccines-provide-immunity-11618258094>

⁸⁵ We note that as of this writing there remains a major unanswered question as to whether and if so to what extent vaccinated persons transmit COVID-19.

estimates in dollar terms. One of the major benefits of vaccination is that it lowers the cost of treating the disease among those who would otherwise be infected and have serious morbidity consequences. The largest part of those costs is for hospitalization and they are very substantial. As discussed later in the analysis we do have data on the average costs of hospitalization of these patients (it is, however, unclear as to how that cost is changing over time with better treatment options). A lesser but still very substantial amount of these morbidity costs is for care of gravely ill patients within the nursing home, but reducing those costs is another benefit we are unable to estimate at this time.

There is a potential offset to benefits that we have not estimated. As long as vaccine supplies do not meet all demands for vaccination, giving priority to some persons over others necessarily means that some persons will become infected who would not have been infected had the priorities been reversed. In this case, however, the priority for elderly persons (virtually all of whom have risk factors) who comprise the vast majority of LTC facility residents, is prioritizing those at higher risk of mortality and severe disease over those whose risk of death is multiple orders of magnitude lower.⁸⁶ As a result, there are some assumptions we make that could overstate benefits should the assumptions be overtaken by adverse events.

The HHS “Guidelines for Regulatory Impact Analysis” explain in some detail the concept of Quality Adjusted Life Years (QALYs).⁸⁷ QALYs, when multiplied by a monetary estimate such as the Value of a Statistical Life Year (VSLY), are estimates of the value that people are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY and VSLY amounts used in any estimate of overall benefits are not meant to be precise, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars.

⁸⁶ The risk of death from infection from an unvaccinated 75 to 84 year old person is 320 times more likely than the risk for an 18- to 29-years old person. CDC, “Risk for COVID-19 Infection, Hospitalization, and Death by Age Group”, at <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html>

⁸⁷ <https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>.

Under a common approach to benefit calculation, we can use a Value of a Statistical Life (VSL) to estimate the dollar value of the life-saving benefits of a policy intervention, such as this rule. We adopt the VSL of approximately \$10.6 million in 2020 as described in the HHS Guidelines, adjusted for changes in real income and inflated to 2019 dollars using the Consumer Price Index. Assuming that the average rate of death from COVID-19 (following SARS-CoV-2 infection) at nursing home resident ages and conditions is 5 percent, and the average rate of death after vaccination is essentially zero, the expected value of each resident receiving the full course of two vaccines who would otherwise be infected with SARS-CoV-2 is about \$530,000 ($\$10,600,000 \times .05$).

Under a second approach to benefit calculation, we can estimate the monetized value of extending the life of nursing home residents, which is based on expectations of life expectancy and the value per life-year. As explained in the HHS Guidelines, the average individual in studies underlying the VSL estimates is approximately 40 years of age, allowing us to calculate a value per life-year of approximately \$540,000 and \$900,000 for 3 and 7 percent discount rates respectively. This estimate of a value per life-year corresponds to 1 year at perfect health. (These amounts might reasonably be halved for average nursing home residents, since non-institutionalized U.S. adults aged 80-89 years report average health-related quality of life (HRQL) scores of 0.753, and this figure is likely to be lower for nursing home residents.⁸⁸) Assuming that the average life expectancy of long-term care residents is five years, the monetized benefits of saving one statistical life would be about \$2.5 million ($\$540,000 \times$ annually for 5 years) at a 3 percent discount rate and about \$3.7 million ($\$900,000 \times$ annually for 5 years) at a 7 percent discount rate. Assuming that the average rate of death from COVID-19 (SARS-CoV-2 infection) at nursing home resident ages and conditions is 5 percent, and the

⁸⁸ Hanmer, J. W.F. Lawrence, J.P. Anderson, R.M. Kaplan, D.G. Fryback. 2006. "Report of Nationally Representative Values for the Noninstitutionalized US Adult Population for 7 Health-Related Quality-of-Life Scores." *Medical Decision Making*. 26(4): 391-400.

average rate of death after vaccination is essentially zero, the expected life-extending value of each resident receiving the full course of two vaccines who would otherwise be infected is \$125 thousand at a 3 percent discount rate and \$185 thousand at a 7 percent discount rate. A similar calculation can be made for staff, who will gain many more years of life but whose risk of death is far smaller since their age distribution is so much younger. Yet another calculation for clients of ICFs-IID would also result in many more years of life but far smaller risks of death since their age distribution is typically far younger than that of LTC residents. It is difficult to ascertain the number of ICF-IID clients that would be infected without vaccination. Deaths from COVID-19 in unvaccinated LTC residents to date are about 130,000, or close to one tenth of the average LTC resident census of 1.4 million, a huge contrast to the handful of deaths in the vaccination results from Israel.⁸⁹ We do not have sufficient data so as to accurately estimate annual resident inflows and outflows over time, but it is clear that several hundred thousand new individuals each year make the total number served during the year far higher than point in time or average counts (see Table 5).

We do know that large numbers of residents or staff were vaccinated through the Pharmacy Partnership, which for nursing home residents relied most heavily on the CVS and Walgreens drug store chains. In its latest report, the Partnership reported that to date it had vaccinated about 2.2 million residents in long-term care facilities, although fewer than two thirds of these had received two doses.⁹⁰ We do know that significant fractions of staff, perhaps one-third or more, have to date declined vaccination when offered.⁹¹ Progress has been very substantial, but many remain unvaccinated among both residents and staff. This interim final

⁸⁹ Deaths are from COVID-19 Nursing Home Data, CMS, Week Ending 2/21/2021, at <https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/>

⁹⁰ See <https://www.cdc.gov/vaccines/covid-19/planning/index.html>

⁹¹ See the discussion and data in the CDC report “Early COVID-19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program – United States, December 2020 – January 2021, at https://www.cdc.gov/mmwr/volumes/70/wr/mm7005e2.htm?s_cid=mm7005e2_x.

rule has significant potential to support further vaccinations as vaccination opportunities from other sources expand.

The preceding calculations address residential long-term care. Long-term residents are a major group within nursing homes and are generally in the nursing home because their needs are more substantial and they need assistance with the activities of daily living, such as cooking, bathing, and dressing. These long-term stays are primarily funded by the Medicaid program (also, through long-term care insurance or self-financed), and the residential care services these residents receive are not normally covered by Medicare or any other health insurance. A second major group within the same facilities receives short-term skilled nursing care services. These services are rehabilitative and generally last only days, weeks, or months. They usually follow a hospital stay and are primarily funded by the Medicare program or other health insurance. The importance of these distinctions is that the numbers of residents in each category are different. The average number of persons in facilities for long-term care over the course of a year is about 1.2 million residents (as is the point-in-time number), and the total number of persons over the course of a year is about 1.6 million. The average number in skilled nursing care over a year is about 200,000 million persons, but the average length of stay is weeks rather than years.⁹² The annual turnover in this group is such that about 2.3 million residents are served each year. There is some overlap between these two populations and the same person may be admitted on more than one occasion. For purposes of this analysis (although we have no documented basis for estimating those numbers), we assume that the expected longevity for each group is identical on average, and that a total of 3.9 million persons are served each year. We further assume that 20 percent of these are new residents each year who must be offered vaccination (most are already vaccinated, as discussed later in the analysis).

⁹² In fact, the average length of stay for skilled nursing care is about 25 days. See MEDPAC, Report to the Congress: Medicare Payment Policy, March 2019, “Skilled nursing facility services,” page 200.

These nursing facilities have about 950,000 full-time equivalent employees. For these persons, the average age is about 50, which creates two offsetting effects: they have more years of life expectancy than residents, but their risk of from COVID-19 death is far lower. For purposes of this analysis, we assume that the vaccination is effective for at least one year, and use a one-year period as our primary framework for calculation of potential benefits, not as a specific prediction but as a likely scenario that avoids forecasting major and unexpected changes that are either strongly adverse or strongly beneficial. If we were adding up totals for benefits we would assume that the risk of death after COVID-19 infection is likely only one-half of one percent (one tenth of the resident rate) or less for the unvaccinated members of this group, reflecting the far lower mortality rates for persons who are mostly in the 30 to 65 year old age ranges compared to the far older residents.⁹³ We assume that the total number of individual employees is 50 percent higher than the full-time equivalent but that only half that number are primarily employed at only one nursing facility, two offsetting assumptions about the number of employees working at each facility (many employees are part-time consultants or the equivalent who serve multiple nursing facilities on a part-time basis). We further assume that employee turnover is 80 percent a year, lower than the results for nurses previously cited. Accordingly, we estimate that 80 percent of 950,000, or 760,000, are new employees each year and must be offered vaccination (again, most are already vaccinated), for a total of 1,710,000 eligible employees over the course of a year.

As for ICFs-IID, there are about 6,000 facilities, serving about 100,000 people at any one time, an average of about 15 people per facility.⁹⁴ The age profile of these clients is similar to that of the adult population at large. Turnover rates are unknown, but likely to be substantial

⁹³ See the previously cited CDC report on risks by age group. In the age intervals used by CDC, the 40-49 year old group is in the middle of typical employment age ranges. The risk of death in this age group is one tenth that of those aged 65-74. We emphasize with round numbers that nothing about these data are fixed and unlikely to change (e.g., as better future treatments are used to treat severe cases).

⁹⁴ By far the largest source of data related to ICF and other IID services is “In-Home and Residential Long-Term Supports and Services for Persons with Intellectual or Developmental Disabilities: Status and Trends 2017”, at https://ici-s.umn.edu/files/aCHyYaFjMi/risp_2017

because these clients have many alternatives. We estimate 80 percent a year for turnover, the same as for nursing facilities. The costs and benefits of COVID-19 vaccination services for this group are roughly comparable to those of nursing home staff. There do not appear to be data on number of staff at these facilities, but based on the nature of the services provided it appears likely that the staff to client ratio is similar to that in other congregate settings (group homes, assisted living facilities), and likely to be about three-fourths of the client population, or about 75,000 full-time equivalent staff, with similar turnover patterns as well. Adding 80 percent to allow for staff turnover, gives a total of 135,000 staff candidates for vaccination.

We have some data on the costs of treating serious illness among the unvaccinated who become infected, are hospitalized, and survive. Among those age 65 years or above, or with severe risk factors, as many as 40 percent of those known to be infected required hospitalization in the first month of the pandemic. Among adults age 21 years to 64 years, about 10 percent of those infected required hospitalization.⁹⁵ For our estimates, we assume a 20 percent hospitalization rate among people aged 65 years or older in nursing homes, reflecting both that their conditions are significantly worse than those of similarly aged adults living independently, and that pre-hospitalization treatments have improved. Of the LTC facility and ICF-IID candidates for vaccination in the first year covered by this rule, about three-fourths are age 65 years or above. Hence, the age-weighted hospitalization rate that we project is about 16 percent. Among those hospitalized at any age, the average cost is about \$20,000.⁹⁶

To put these cost, benefit, and volume numbers in perspective, vaccinating one hundred previously unvaccinated LTC residents who would otherwise become infected with SARS-CoV-

⁹⁵ There are few data sources for this statistic and, thus, it may be out of date. See MMWR, “Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019—United States, February 12-March 28, 2020”, April 3, 2020, at https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm#T2_down.

⁹⁶ This is not a robust estimate, but is supported by several sources. See for example Jiangzhuo Chen et al, “Medical costs of keeping the US economy open during COVID-19,” Scientific Reports, Nature.com, July 19 2020, at <https://pubmed.ncbi.nlm.nih.gov/32743613/>, and Michel Kohli et al, “The potential public health and economic value of a hypothetical COVID-19 vaccine in the United States: Use of cost-effectiveness modeling to inform vaccination prioritization,” Science Direct, February 12, 2021, at <https://pubmed.ncbi.nlm.nih.gov/33483216/>.

2 and have a COVID-19 illness would cost approximately \$54,200 ($\542×100) in paperwork, education, and vaccination costs. Using the VSL approach to estimation would produce life-saving benefits of about \$2,650,000 for these 100 people ($\$530,000 \times 100 \times .05$), again assuming the death rate for those ill from COVID-19 of this age and condition is one in twenty.

Reductions in health care costs from hospitalization would produce another \$320,000 ($\$20,000 \times 100 \times .16$) in benefits for this group assuming that 16% would otherwise be hospitalized.

However, this comparison should be taken as necessarily hypothetical and contingent due to the analytic, data, and uncertainty challenges discussed throughout this regulatory impact assessment. As the discussion of other patient groups covered by this rule demonstrates, they present similar if not identical magnitudes of both costs and benefits for affected individuals (benefits from staff vaccinations, however, are far lower) Consequently, the primary medium- to long-run benefit-cost issue is not the general magnitude of likely effects on those who get vaccinated as a result of the rule, but the difficult questions of estimating (1) likely numbers of individuals in both client and staff categories who are likely to be unvaccinated when the rule goes into effect and (2) to be willing to accept vaccination in the coming months and years.⁹⁷

Of particular importance is that the vaccination rates and raw numbers of people vaccinated take into account that in total only about half of those who will be residents and clients in these facilities at some time during the year have already been residents or clients during the months served by the Pharmacy Partnership effort. For example, our estimated vaccination rate as of March 31, 2021, for LTC residents assumes that about 90 percent of the residents in January through March will have been vaccinated. But given the turnover expected during the rest of the year, only about 70 percent of the annual total will have been vaccinated by the end of 2021, or by the end of the first year including the first quarter of 2022. As a result, about 3.6 million persons will be vaccination candidates subject to this rule over the first year.

⁹⁷ For a survey of the evidence on this issue, see Gillian K. Steelfisher et al, “An Uncertain Public—Encouraging Acceptance of Covid-19 Vaccines,” *The New England Journal of Medicine*, March 3, 2021 .

Some of these persons may have been vaccinated elsewhere, but the facilities regulated under this rule will need to query each incoming resident and it is likely that as many as a third of these will be candidates for COVID-19 vaccination. A major caution about these estimates: none of the sources of enrollment information for these programs regularly collect and publish information on client or staff turnover during the course of a year. The estimates here are based on inferences from scattered data on average length of stay, mortality, job vacancies, news accounts, and other sources that by happenstance are available for one type of facility or type of resident or another. Nor do we have data on the number of persons in these settings who will be vaccinated through other means during the remainder of the year.

There are also dimensions of positive and negative benefits in the medium- to long-run that we have not been able to estimate. For example, there is insufficient evidence as to whether the current or reasonably foreseeable vaccines will maintain their protective efficacy for more than six months.

Until very recently, demand for COVID-19 vaccination has exceeded supply throughout the U.S.⁹⁸ Especially in previous months, vaccination distribution policies giving priority to various groups (for example, aged, health care workers, and other essential services workers) has meant that those given priority have benefited to some extent at the expense of those in lower priorities. Regardless of priorities, we know that younger persons are much less likely to experience hospitalization or death after infection. For example, the risk of death among infected persons age 65 to 74 years is ten times greater than the risk of death among infected persons age 40 to 49 years. Yet the average years of remaining life among younger persons at these ages is far greater than among older persons at higher ages. Age, however, is not anywhere near a perfect indicator of risk since, for example, health care workers and those with immune

⁹⁸ The shortage issue has now largely been addressed, as is well illustrated in the recent removal of age restrictions designed to give highest priority in using limited vaccine supplies to the elderly and health care workers. See, for example, news stories: <https://www.abc27.com/news/health/coronavirus/official-biden-moving-vaccine-eligibility-date-to-april-19/>.

system disorders face elevated risks from exposure. Sorting out all these factors to reach either a qualitative or quantitative estimate of net benefits from any particular policy is extremely complex and is one reason why vaccination priorities have differed among the states and over time.

All these data and estimation limitations apply to even the short-term impacts of this rule, and major uncertainties remain as to the future course of the pandemic, including but not limited to vaccine effectiveness in preventing disease transmission from those vaccinated, and the long-term effectiveness of vaccination.

E. Other Effects

1. Sources of Payment

We anticipate that virtually all of the costs of this rule will be reimbursed from funds already appropriated under the CARES Act and the American Rescue Plan Act of 2021. For example, the amounts provided in the Provider Relief Fund is \$7.4 billion, many times more than the relatively small costs of this rule. As previously discussed, if there are treatment cost savings to hospitals and other care providers as a result of the vaccinations that will be made due to this rule, the treatment cost savings would in turn result in savings to payers. It is likely that half or more of these savings would primarily accrue to Medicare given the elderly or disability status of most clients and Medicare's role as primary payer, but there would also be substantial savings to Medicaid, private insurance paid by employers and employees, and private out-of-pocket payers including residents.

2. 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 many LTC facilities and most ICFs-IID 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 business (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 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.

The average annual cost of a nursing home stay is about \$271.98 per day or about \$100,000 per year.⁹⁹ As estimated previously, the average annual cost of this rule is about \$24.70 per resident or staff person in the first year. This cost does not approach the 3 percent threshold. For ICFs-IID, one estimate of average annual costs per client is \$140,000, also a level at which this rule does not approach the 3 percent threshold.¹⁰⁰ Moreover, since most or all of these costs will be reimbursed through the CARES Act or other COVID-19 funding sources, the financial strain on these facilities should be negligible and the likely net effect positive. Considering the cost savings from treating seriously ill residents, the financial impact is likely to be positive. Therefore, the Department has determined that this interim final rule will not have a significant economic impact on a substantial number of small entities and that a final RIA is not required. Finally, this IFC 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.

3. Small rural hospitals.

Section 1102(b) of the Social Security Act requires us to prepare a RIA if a proposed 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. Because this rule has no

⁹⁹ See Marcum Accountants & Advisors, A Five Year Nursing Home Statistical Analysis (2014 to 2018), at <https://www.marcumllp.com/wp-content/uploads/marcum-five-year-nursing-home-statistical-analysis-2014-2018.pdf>

¹⁰⁰ See In-Home and Residential Long-Term Supports and Services for Persons with Intellectual or Developmental Disabilities: Status and Trends 2017, op cit, page 77.

direct effects on any hospitals, the Department has determined that this interim final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. This interim final rule is also exempt because that provision of law only applies to final rules for which a proposed rule was published.

4. 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 2021, that threshold is approximately \$158 million. This rule does contain mandates on private sector entities, and we estimate the resulting amount to be about the same as this threshold in the first year. This IFC was not preceded by a notice of proposed rulemaking, and therefore the requirements of UMRA do not apply. The information in this RIA and the preamble as a whole would, however, meet the requirements of UMRA.

5. 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 requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Nothing in this rule will have a substantial direct effect on state or local governments, preempt state laws, or otherwise have federalism implications.

F. Alternatives Considered.

As discussed earlier in the preamble, a major substantive alternative that we considered was to require vaccination activities (education and offering) for all persons who may provide paid or unpaid services, such as visiting specialists or volunteers, who are not on the regular payroll on a weekly or more frequent basis. That is, individuals who work in the facility infrequently. We also considered including visitors, such as family members. All these

categories present major problems for compliance, enforcement, and record-keeping, as well as a multitude of complexities related to visit frequency, resident exposure, and vaccination management. Furthermore, the efficacy of such a policy would be difficult to establish. For example, vaccinating a one-time visitor on the day of their visit would not improve resident safety because the vaccine is not instantly effective upon administration. There are also ethical issues related to potential discouragement of visiting volunteers or family members. Instead, we believe that such decisions are best left to each facility, in consideration of CMS and CDC guidance. Our expectation is that vaccination of regular visitors in any of these categories will be encouraged, whether or not the vaccinations are offered by the facility itself.

G. Accounting Statement and Table.

The Accounting Table summarizes the quantified impact of this rule. It covers only one year because there will likely be many 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 the RIA and the preamble as a whole, there are major uncertainties as to the effects of COVID-19 on nursing and other congregate living facilities as well as the nation at large. For example, the duration of vaccine effectiveness in preventing infection, reducing disease severity, reducing the risk of death, and preventing disease transmission by those vaccinated are all currently unknown. These uncertainties also impinge on benefits estimates. For those reasons we have not quantified into annual totals either the life-extending or medical cost-reducing benefits of this rule, and have used only a one-year projection for the cost estimates in our Accounting Statement (our estimates are for the last nine months of 2021 and the first three months of 2022). We welcome comments on all of our assumptions and welcome any additional information that would narrow the ranges of uncertainty.

Table 7: Accounting Statement: Classification of Estimated Costs and Savings (\$ millions)

Category	Primary Estimate	Lower Bound	Upper Bound	Units		
				Year Dollars	Discount rate (%)	Period Covered
Benefits: Lives Extended (not annualized or monetized)				2020	7%	First year
Reduced Medical Expenditures (not annualized or monetized)				2020	3%	First year
Costs: Annualized Monetized (\$million/year)	159	119	199	2020	7%	First year
	159	119	199	2020	3%	First year
Cost Notes: Administrative costs from increased efforts to vaccinate residents and staff						
Transfers	None					

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

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 22, 2021.

List of Subjects in 42 CFR Part 483

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 483 as set forth below:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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

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

2. Section 483.80 is amended by—

a. Revising the heading for paragraph (d);

- b. Adding paragraph (d)(3);
- c. Removing the word “and” at the end of paragraph (g)(1)(vii);
- d. Revising paragraph (g)(1)(viii); and
- e. Adding paragraph (g)(1)(ix).

The revisions and additions read as follows:

§ 483.80 Infection control.

* * * * *

(d) *Influenza, pneumococcal, and COVID-19 immunizations--* * * *

(3) *COVID-19 immunizations.* The LTC facility must develop and implement policies and procedures to ensure all the following:

(i) When COVID-19 vaccine is available to the facility, each resident and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;

(ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;

(iii) Before offering COVID-19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine;

(iv) 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 administration of any additional doses;

(v) The resident, resident representative, or staff member has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision;

(vi) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and

(B) Each dose of COVID-19 vaccine administered to the resident; or

(C) If the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal; and

(vii) The facility maintains documentation related to staff COVID-19 vaccination that includes at a minimum, the following:

(A) That staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccine;

(B) Staff were offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine; and

(C) The COVID-19 vaccine status of staff and related information as indicated by the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN).

* * * * *

(g) * * *

(1) * * *

(viii) The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and

(ix) Therapeutics administered to residents for treatment of COVID-19.

* * * * *

3. Section 483.430 is amended by adding paragraph (f) to read as follows:

§ 483.430 Condition of participation: Facility staffing.

* * * * *

(f) *Standard: COVID-19 vaccines.* The facility maintains documentation related to staff that includes at a minimum, all of the following:

(1) Staff were provided education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine.

(2) Staff were offered COVID-19 vaccine or information on obtaining the COVID-19 vaccine.

4. Section 483.460 is amended by redesignating paragraph (a)(4) as paragraph (a)(5) and adding new paragraph (a)(4) to read as follows:

§ 483.460 Conditions of participation: Health care services.

(a) * * *

(4) The intermediate care facility for individuals with intellectual disabilities (ICF/IID) must develop and implement policies and procedures to ensure all of the following:

(i) When 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 member has already been immunized.

(ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine.

(iii) Before offering COVID-19 vaccine, each client or the client's representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine.

(iv) In situations where COVID-19 vaccination requires multiple doses, the client, client's representative, or staff member is provided with current information regarding each additional dose, including any changes in the benefits or risks and potential side effects associated with the COVID-19 vaccine, before requesting consent for administration of each additional doses.

(v) The client, client's representative, or staff member has the opportunity to accept or refuse COVID-19 vaccine, and change their decision.

(vi) The client's medical record includes documentation that indicates, at a minimum, the following:

(A) That the client or client's representative was provided education regarding the benefits and risks and potential side effects of COVID-19 vaccine; and

(B) Each dose of COVID-19 vaccine administered to the client; or

(C) If the client did not receive the COVID-19 vaccine due to medical contraindications or refusal.

* * * * *

Dated: May 10, 2021.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2021-10122 Filed: 5/11/2021 11:15 am; Publication Date: 5/13/2021]