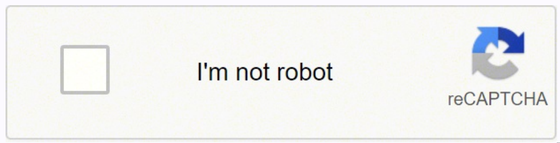

Next

Interim report aged care

Australian Government | myagedcare

Summary of My Aged Care System Changes

20 January 2020

This summary document is intended to assist service providers and assessors in understanding the changes made to the My Aged Care system on 20 January 2020.

This release is focussed on delivering the remainder of the budget measures announced as part of the 2018/19 Budget and high priority system enhancements to improve the usability of the My Aged Care system. The changes include:

- Introduction of the *Apply for an Assessment Online* form on the My Aged Care website to enable consumers to register with My Aged Care and apply for their first assessment online as an alternative to calling the My Aged Care contact centre.
- Consumers will be able to nominate representatives through the *Apply for an Assessment Online* form, and assessors can complete the setup of these relationships in the assessor portal and myAssessor application.
- The myAssessor application will be enhanced to enable assessors to register and set up regular and authorised representatives in both online and offline mode.
- Introduction of an annual notification in the provider portal to remind home care providers to review or update home care pricing information for their services.
- Improvements to the information available to consumers and assessors when searching for services by enabling service providers to indicate whether they offer different specialised service offerings against each service.
- Availability of information as provided by Commonwealth Home Support Programme (CHSP) providers about clients in service prior to 1 July 2015.
- Introduction of myGovID as a supported login option for assessors and providers when accessing the My Aged Care portals, in preparation for the phasing out of AUSkey in March 2020.

Please note: If accessing this document electronically, clicking on the changes above will take you to the relevant section that provides further information on the change.

All relevant guidance documentation (including user guides and quick reference guides) have been updated to support this system release and are available on the department's website.

A short summary is available at the end of this document outlining which guidance documents have been updated as part of this release.

For further information, go to My Aged Care
1800 836 799 | www.agedcare.health.gov.au/myagedcare

Response to aged care royal commission interim report.

CDC has posted a LTC facility toolkit “Preparing for COVID-19 Vaccination at your Facility” at ��vaccines/covid-19/toolkits/long-term-care/. 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. Accordingly, we estimate that 80 Start Printed Page 26333percent 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. 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. 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 2021. 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 to ensure that each resident and staff member is educated about the COVID-19 vaccine. 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. When an individual receives the vaccine, they should also receive a v-safe information sheet telling them how to enroll in v-safe. 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. 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. V. 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). 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. 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. Table 6 summarizes the overall cost estimates. 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 Start Printed Page 26319United 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. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)). 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. 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. The first year burden would be 62,400 hours (4 × 15,600) at an estimated cost of $5,865,600 ($376 × 15,600). For the IPs in all 15,600 LTC facilities, the burden would be 327,600 hours (21 hours × 15,600 facilities) at an estimated cost of $21,949,200 ($1,407 × 15,600). A. According to Table 1 above, the total hourly cost for an RN is $67. 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. Individualized counseling, resident meetings, staff meetings, posters, bulletin boards, and e-newsletters are all approaches that can be used to provide education. 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. 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-2 and have a COVID-19 illness would cost approximately $54,200 ($542 × 100) in paperwork, education, and vaccination costs. 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. 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. 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. For all 5,772 ICFs-IID, the total burden for the administrator would be 17,316 hours (3 × 5,772 facilities) at an estimated cost of $1,627,704 ($282 × 5,772 facilities). 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. (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. It also requires LTC facilities to report COVID-19 vaccination status of residents and staff to the Centers for Disease Control and Prevention (CDC). 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. What works best will depend on the circumstance of the resident and the best method for conveying the information and answering questions. 2. 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. 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. 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. 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. For all LTC facilities, the annual burden would be 93,600 (6 hours × 15,600) hours at an estimated cost of $6,271,200 ($402 × 15,600). 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. 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). Thus, for each ICF-IID to meet this requirement would require 6 burden hours at an estimated cost of $402 ($67 × 6 hours). 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. 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. The low likelihood of severe side effects should be included in this education. 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)). 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. The accuracy of our estimate of the information collection burden.Start Printed Page 26322 The quality, utility, and clarity of the information to be collected. 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. 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. 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. 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. Provisions of the Interim Final Rule 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. 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. 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. 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. 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. According to Table 1 above, the total hourly cost for a financial clerk of $41. 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. 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). 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. 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. 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. 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. 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. It is difficult to ascertain the number of ICF-IID clients that would be infected without vaccination. We request public comment on whether states are collecting COVID-19 vaccination data already, through other mechanisms. 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. 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. 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. 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. 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 Start Printed Page 26308vaccination program. 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. 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. 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”). There are major uncertainties in these estimates. Moving Forward For the reasons discussed above, it is critically important that we implement the policies in this IFC as quickly as possible. 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. CMS recognizes that during the public health emergency “active treatment” may need to be modified. 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. Internal CDC data shows that 99 percent of participating SNFs had held their 3rd (final) clinic as of March 15, 2021. 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 PHSA, the Secretary determined that a PHE exists for the United States to aid the nation's health care community in responding to COVID-19. 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 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. 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. These regulations have been revised and added to since that time, principally as a result of legislation or a need to address specific issues. That said, resident turnover within a year may be significant, possibly up to 40 percent based on internal CMS estimates. Total cost of the educational efforts themselves would be approximately $28,442,000 (849,000 persons × .5 hours × $67 hourly cost). The total costs used in this analysis are indicated in the chart below. 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, 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. 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 on facility administrators, clinical leadership, and health departments. 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. All of the concerns that warrant immediate COVID-19 vaccination rulemaking for LTC facilities are also applicable to ICFs-IID. If the total cost after doubling resulted in .50 or more, the cost was rounded up to the next dollar. 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. 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). End Amendment Part The revisions and additions read as follows: Infection control. 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 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. This IFC aims to ensure that all LTC facility residents, ICF-IID clients, and the staff who care for them, are provided with ongoing access to vaccination against COVID-19. 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. 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. Do policies include residents, clients and staff? We welcome comments that might improve these estimates. 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. 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 also request comment on inequities in COVID-19 preventive care that may have been experienced by LTC facility residents and ICF-IID clients. LTC administrators and clinical leadership are encouraged to track vaccination coverage in their facilities and adjust communication with residents and staff accordingly. 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 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. 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. 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. The IP would need to work with the medical director and DON to develop and finalize the policies and procedures. This would require that the RN to retrieve the client's medical record and document the required information. 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). 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. People living and working in these living situations may have challenges with social distancing and other mitigation measures, like mask use and handwashing, that help to prevent the spread of SARS-CoV-2. This requirement and burden will be submitted to OMB under OMB control number 0938-1363.Start Printed Page 26317 B. 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). The variety and prevalence of comorbidities in individuals served that may increase their risk of severe illness from COVID-19. For all ICFs-IID, the documentation requirements in this IFC this would require 17,316 burden hours (3 hours × 5,772 facilities) at an estimated cost of $709,956 annually (17,316 hours × $123). Revising the heading for paragraph (d); End Amendment Part Start Amendment Partb. 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. 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). 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 × .05). 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. Clients and residents often live in close quarters. Collins Health and Human Services Commission Executive Council Meetings Process Improvement Records & Statistics Vision & Mission Your Rights News Contact Restraint and the Royal Commission Interim Report See What Is And What Is Not Restraint See Infection Prevention and Control Don't risk waiting until the end of 2020 for the final report. 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. 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. Immunization education, delivery, and reporting for influenza and pneumococcal vaccines are already a routine part of LTC facilities' infection control and prevention plans. 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. 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. That is, individuals who work in the facility infrequently. 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. 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. We analyze both the costs of the required actions and the payment of those costs. Facilities reporting vaccinations to the NHSN Long-Term Care Facility Component [49] 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. In subsequent years the burden for all facilities would be 34,632 (6 × 5,772) burden hours at an estimated cost of $2,320,344 (6 × $67 × 5,772). There are also ethical Start Printed Page 26335issues related to potential discouragement of visiting volunteers or family members. 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. For the DON, we have estimated that the development of policies and procedures would also require 4 hours. Start Preamble Start Printed Page 26306 Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS). 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. Revising paragraph (g)(1)(viii); and End Amendment Part Start Amendment Parte. 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. Updates to CDC's COVID-19 Vaccination Program Provider Agreement Requirements can be located on CDC's website.[40] Start Printed Page 26314 2. 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. The costs and benefits of COVID-19 vaccination services for this group are roughly comparable to those of nursing home staff. 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. E. 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 × $94). 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. What other impediments do staff face in getting access to vaccines? 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 does 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 acknowledge the diversity and complexity of the needs of congregate living 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. 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. 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. 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. CMS continues to encourage individuals not to submit duplicative comments. The LTC facility must also report the therapeutics administered to residents for treatment of COVID-19. 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. As explained in the HHS Guidelines, the average Start Printed Page 26332individual 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. Any additional costs are minor and are discussed in more detail in the RIA below. 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. 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. 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). For the initial education, the ICF-IID would be required to develop educational materials by reviewing available resources on COVID-19 vaccines. 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). We further assume that employee turnover is 80 percent a year, lower than the results for nurses previously cited. For subsequent years, the IP would need to review the policies and procedures and make any updates or changes to them. 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. Long-Term Care Facilities 1. Thus, for each LTC facility to meet this requirement would require 6 burden hours at an estimated cost of $402 (6 × $67). 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. 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. This information is also included on FDA fact sheets. For each LTC facility, we estimate that the burden for this activity would be 6 hours at an estimated cost of $246 ($41 × 12 × .5). 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. 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. 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. 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. By regular mail. 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). Most LTC facilities participated in the Pharmacy Partnerships but the Partnerships concluded in March 2021. 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. On March 13, 2020, the President of the United States declared the COVID-19 pandemic a national emergency. 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. The burden for each LTC facility would be 12 hours at an estimated cost of $804 (12 hours × $67) for the IP. 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. 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. On December 11, 2020, the U.S. Food and Drug Administration issued the first Start Printed Page 26312EUA 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. Some resident education can take place in group settings and some education will take place on a one-to-one level. Internal CDC data shows that 99 percent of participating SNFs had held their third (final) clinic as of March 15, 2021. 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. Vaccine materials specific to each vaccine are located on CDC and FDA websites. We believe that the education provided to staff and residents or resident representatives will be identical or virtually the same. We anticipate evaluating public input and evolving science before finalizing any requirements. 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. There are also dimensions of positive and negative benefits in the medium- to long-run that we have not been able to estimate. 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. The requirements and burden will be submitted to OMB under OMB control number 0938-New. 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. 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. 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. 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. 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). 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. 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. 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. 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. Every person who receives a COVID-19 vaccine receives a vaccination record card noting which vaccine and the dose received. 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. 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. 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. In ICFs-IID, consent or assent for vaccination should be obtained from clients or representatives and documented in the client's medical record. 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. 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. 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. 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. Some may not understand the dangers of the virus, or be able to independently comply with mitigation measures. 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. Those who need help with activities of daily living cannot maintain their distance from staff and caregivers. Considering the cost savings from treating seriously ill residents, the financial impact is likely to be positive. Does your program or facility have vaccine policies? 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. An ICF-IID administrator would likely work with the RN and need to approve the final educational material. 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. We estimate 80 percent a year for turnover, the same as for nursing facilities. The requirements and burden will be submitted to OMB under OMB control number 0938-1363 (Expiration Date 6/30/2022). Based upon our experience with LTC facilities, we believe that some of these facilities have already developed the required policies and procedures. 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. 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. Vaccines may be administered onsite or at other appropriate locations. 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 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 × .2). How have they been helpful to your facility or program? 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. 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. However, they have not continued to collect or report these data after their clinics concluded. 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). 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. (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. There may be posters and flyers announcing appointments for vaccine clinic days or other vaccination opportunities. For the first year, the burden would be 62,400 (4 × 15,600) at an estimated cost of $10,545,600 ($676 × 15,600). 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. Intermediate Care Facil

care inequities faced by the general population, discussed further in Section I.D. of this rule, are also seen within LTC facilities. Currently, low rates of voluntary use of NHSN for vaccination reporting precludes accurate estimates of vaccine coverage. Re-vaccination or use of new and improved vaccines would likely maintain the effectiveness of vaccination for residents and staff. 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). Removing the word "and" at the end of paragraph (g)(1)(vii); End Amendment Part Start Amendment Partd. 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. 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). CDC has information describing IPC considerations for residents of long-term care facilities with systemic signs and symptoms following COVID-19 vaccination. 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. 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. Similar to influenza vaccines, if there is a manufacturing delay, we ask the facility to provide sufficient evidence of such. 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. 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. The infection prevention and control plan is designed to allow for documentation of vaccine efforts. 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. 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 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 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. 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. These nursing facilities have about 950,000 full-time equivalent employees. ICF-IID Clients New § 483.460(a)(4)(iii) requires that ICF-IID clients, or their representatives are educated about vaccination against COVID-19. ICFs-IID and COVID-19 ICFs-IID, residential facilities that provide services for people with disabilities, vary in size. Individuals who enroll will receive regular text messages directing them to surveys where they can report any problems or adverse reactions 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. While there are large numbers of such record notations to be made, we estimate that they take only a few seconds per record. 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. Individuals and states are not included in the definition of a small entity. 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. 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 note that we are permitting but not requiring LTC facilities to provide the vaccine directly. Staff should also be informed about ongoing opportunities for vaccination. Table 3—Total Burden for COI Requirements for All ICFs-IIDCOI requirementFirst yearSubsequent yearsBurden hoursCostsBurden hoursCosts§ 483.460(a)(4) Developing the policies and procedures77,922$5,688,30634,632$2,320,344§ 483.460(a)(4)(ii), (iii), and (iv) Education requirements75,0365,027,41234,6322,320,344§ 483.460(a)(4)(v) and (f) Documentation requirements17,316709,95617,316709,956Totals170,27411,425,67486,5805,350,644 Start Printed Page 26327 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). 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. 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. Home Services Providers Business Regulations About Budget & Planning Health & Human Services System Strategic Plans 2021-2025 Community Engagement Contact Us Events Jobs at HHS Leadership Advisory Committees Executive Teams & Organizational Chart Chief Policy and Regulatory Officer, Jordan Dixon Associate Commissioner for Managed Care, Shannon Kelley Chief Audit Executive, Nicole Guerrero Chief Financial Officer, Trey Wood Chief Medical Director, Dr. Ryan D. We estimate that this would require one half-hour per month per facility. 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. Start Printed Page 26320Furthermore, 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. 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. There is some overlap between these two populations and the same person may be admitted on more than one occasion. 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). Pursuant to section 319 of the PHSA, the determination that a PHE continues to exist may be renewed at the end of each 90-day period.[1] 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. 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. 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. 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] 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. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. 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). In subsequent years, all 15,600 LTC facilities would have the same burden. Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 12, 2021. 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). Aggregate COVID-19 vaccination data collected as a result of this rulemaking will be made available to the public in the future. Follow the "Submit a comment" instructions. 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). 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. (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. 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-19 vaccine. Adding paragraph (g)(1)(ix). The program should provide COVID-19 vaccines, when available, to all residents and staff who choose to receive them. Adding 80 percent to allow for staff turnover, gives a total of 135,000 staff candidates for vaccination. DATES: These regulations are effective on May 21, 2021. 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. We do not intend to prohibit such extensions and encourage facilities to educate and offer vaccination to these individuals as reasonably feasible. The Pharmacy Partnership program was designed as time-limited effort designed to quickly vaccinate thousands of facility residents per week. This would require that a staff person document that these tasks were accomplished. 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. 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. 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. 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). ICF-IID staff are integral to the function of the ICFs-IID and the health and well-being of clients. 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. 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. 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. Turnover rates demonstrate there will be an ongoing need for new resident or staff vaccinations. 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 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. 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. 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. 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. * * * * * Start Amendment Part3. 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. 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. 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. 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. 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). 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. These requirements are necessary to help protect the health and safety of ICF-IID clients and LTC facility residents. 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). 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. See Table 2 below. The largest part of those costs is for hospitalization and they are very substantial. 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). 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. 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. Hence, the age-weighted hospitalization rate that we project is about 16 percent. 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. 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). 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. 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. 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. F. 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. 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. Facilities may find that reward techniques, among other strategies, may help. In this way, the vaccination status of every LTC facility will be known on a weekly basis. It would also ensure we can identify and address barriers to completing a vaccination series, such as missed or declined second doses. 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). 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. 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. 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, 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. We welcome comments on all of our assumptions and welcome any additional information that would narrow the ranges of uncertainty. 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. 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 person, compared to 365 if one person left each day and was replaced that same day by another person. 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 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. Regulatory Impact Analysis A. 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. Pharmacy partners reported vaccination clinics they held in LTC facilities, and they have shared these data with CDC. 4. 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. 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). Thus, for each ICF-IID, the burden for the RN would require 13 burden hours at an estimated cost of $871 (13 × $67). 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 estimates in dollar terms. 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. 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. This interim final rule has significant potential to support further vaccinations as vaccination opportunities from other sources expand. On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. Much of the immediate need for LTC resident and staff education has already been accomplished through the Pharmacy Partnership for Long-Term Care Program. 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. 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. 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. 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. Table 6—Estimate of Total CostsCost categoryCosts in first yearCosts in succeeding yearsDeveloping NF Policies & Procedures$38,360,000$12,542,000Developing Education Materials for Residents and Staff4,181,000NAKeeping Vaccine Information Up-to-Date6,271,0006,271,000Documentation Requirements3,838,0003,838,000Start Printed Page 26331NHSN Reporting to CDC and CMS27,175,00027,175,000Subtotal, NF Information Collection79,825,00049,826,000ICF-IID Information Collection11,426,0005,351,000Subtotal Information Collection91,251,00055,177,000Educating Residents & Staff *35,220,00026,415,000Providing Vaccine to Residents and Staff **23,460,00017,595,000Keeping Records of the Above Activities9,125,0005,518,000Total Costs159,056,000104,705,000* 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). Additional adverse events following vaccination may be reported to VAERS. 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. 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). 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. These services are rehabilitative and generally last only days, weeks, or months. 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. This collaboration is intended to enhance the opportunities for vaccine uptake in congregate living settings. Nonetheless, many facilities across the country are educating staff, residents, and resident representatives; participating in vaccine distribution programs; and voluntarily reporting vaccine administration. (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. 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. 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 understand, including in an alternative format or in a language that the resident can Start Printed Page 26324understand. 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. The second large cluster of costs are for the required resident, client, and staff education. 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. 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. 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. 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. 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. 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. ACTION: Interim final rule with comment period. 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. Age, however, is not anywhere near a perfect indicator of risk since, for example, health care workers and those with immune system disorders face elevated risks from exposure. 3. We estimate that the average cost of a vaccination is what the Government pays under Medicare: $20 × 2 = $40 for two doses of a vaccine, and $20 × 2 for vaccine administration of two doses, for a total of $80 per resident. Despite the increased use of nursing homes by minority residents, nursing home care remains highly segregated. 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. This cost does not approach the 3 percent threshold. 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. The rate of employee sharing between congregate living facilities and the rate of employee turnover. 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. 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). 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 potential side effects of the COVID-19 vaccine. 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. 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. 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. 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. 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). Where such data are available, we are requesting respondents include data indicating: The rate of admission to congregate living facilities. Turnover rates are unknown, but likely to be substantial because these clients have many alternatives. Both the medical director and the DON would need to have meetings

with the Start Printed Page 26323P to discuss the development, evaluation, and approval of the policies and procedures. Clients of ICFs-IID and their representatives must be offered education about vaccine immunization development, administration, and evaluation. Deaths from COVID-19 in unvaccinated LTC residents to date are about 130,000, or close to one third of the total number served during the year far higher than point in time or average counts (see Table 5). According to Table 1 above, the total hourly cost of a financial clerk is $41. Over 569,000 individuals have lost their lives to COVID-19 in the United States as of April 27, 2021,[60] including more than 130,000 LTC facility residents, or close to one tenth of the 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 EUA fact sheet explains the risks or potential side effects and benefits of the COVID-19 vaccine they are receiving and what to expect. CDC has recommended that 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 to be independently scheduled or travel to public offsite vaccination opportunities. While congregate living settings are also often part of a state's and home and community-based services (HCBS) infrastructure. 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. 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). Facilities can determine where they keep the documentation that demonstrates educational efforts and offering the vaccine to staff. 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. Thus, we expect that required education would be in a language that the resident or the resident representative can understand. (v) The client, client's representative, or staff member has the opportunity to accept or refuse COVID-19 vaccine, and change their decision. 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. 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 estimate but as a likely scenario that avoids forecasting major and unexpected changes that are either strongly adverse or strongly beneficial. According to Table 1 above, the IP's total hourly cost is $67. Clients and their representatives (on behalf of the client) have the right to refuse vaccination. 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. 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. But this huge achievement depends critically on success in vaccination of nursing home residents and staff. Therefore, CDC cannot calculate the percentages of residents and staff vaccinated in each facility via the Federal Pharmacy Partnership data. 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. The preceding calculations address residential long-term care. 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 residents, clients, and staff. 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. 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 x $67). All of these aggregate costs can be converted to per person numbers since it is individual persons who are vaccinated. 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. III. You may submit electronic comments on this regulation to . LTC facilities are already required to provide information to an alternate format or language the resident or resident representative understands. There may be posters and flyers announcing appointments for vaccine clinic days or other opportunities to be vaccinated. Staff at ICFs-IID should follow the recommended IPC practices described on CDC's website for ICFs-IID. During the PHE, some 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. This interim final rule will close a gap in current regulations, which are silent on the subject of vaccination to prevent COVID-19. Ensuring the health and safety of all Americans, including Medicare and Medicaid beneficiaries, and health care workers is of primary importance. End Authority Start Amendment Part Part. For example, the risk of death among infected persons age 65 to 74 years is ten times greater Start Printed Page 26334than the risk of death among infected persons age 40 to 49 years. FDA's EUA website includes letters of authorization and fact sheets and these should be checked for any updates that may occur. This rule establishes penalties for non-compliance, in order to require facilities to educate about and offer vaccination to residents and staff. 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. Staff should be instructed about the importance of vaccination for residents, their personal health, and community health. 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. Table 4—Total COI burden for LTC Facilities and ICFs-IID in This IFCType of facilityFirst yearSubsequent yearsBurden hoursCostsLTC Facility1,07,600$79,825,200780,000$49,820,400ICFs-IID170,27411,425,67486,58605,350,641Totals1,277,87491,250,874866,58055,177,041 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. 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 settings, such as adult day health programs, either in the licensing or certification requirements or elsewhere? 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. 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. Start List of Subjects List of Subjects in 42 CFR Part 483 End List of Subjects For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 483 as set forth below: Start Part PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES End Part Start Amendment Part. We estimate that the burden to the LTC facilities will be similar in subsequent years due to the large turnover in these facilities. B. 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. In addition, we are requiring facilities to offer COVID-19 vaccines to residents, clients, and staff. 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. Data on vaccine uptake will be important to understanding the impact of vaccination on SARS-CoV-2 infections and transmission in nursing Start Printed Page 26318homes.[48] This understanding, in turn, will help CDC make changes to guidance to better protect residents and staff in LTC facilities. Thus, for each LTC facility to meet this requirement would require 6 burden hours at an estimated cost of $368 (6 x $67). 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. Staff should be provided education on culturally appropriate ways to educate and share information with clients to prevent misinformation, confusion, or loss of credibility. Administration of any vaccine includes appropriate monitoring of vaccine recipients for adverse reactions. Accounting Statement and Table The Accounting Table summarizes the quantified impact of this rule. At § 483.460(a)(4)(i), in accordance with accepted professional standards and practices, the LTC facility must maintain medical records on each resident that are complete and accurately documented. 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). 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). I. 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. End Signature End Supplemental Information [FR Doc. 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 Start Printed Page 26313COVID-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. This toolkit provides LTC administrators and clinical leadership with information and resources to help build vaccine confidence among residents, clients, and staff. They may also provide it indirectly, such as through arrangement with a pharmacy partner or local health department. 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. 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. 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. 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. 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 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 respect their input on ways that CMS and HHS can further support safety and reduce the risk of infection moving forward. At new § 483.460(l), 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. These challenges create potential disparities in vaccine access for those residing in LTC facilities and ICFs-IID. We estimate that this would require 4 hours for both the medical director and DON. 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 to meet § 483.460(a)(4)(i). 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 nationwide, including LTC facility pharmacy locations. It also assumes that only about half of year-end residents will have been residents at the beginning of the year will have been vaccinated. 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 2021, that threshold is approximately $158 million. Start Further Info 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. The average number in skilled nursing care on any one day is about 1.2 million residents in LTC facilities, but the average length of stay is weeks rather than years.[92] The annual turnover in this group is such that about 2.5 million residents are served each year. The importance of these distinctions is that the numbers of residents in each category are different. Despite the limited data available regarding COVID-19 cases or outbreak in ICFs-IID, we recognize the unique concerns for these facilities and their staff. We estimate that follow are largely based on upon our experience with LTC facilities. 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. 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"). We strongly encourage facilities, when the opportunity exists and resources allow, to provide vaccination to all individuals who provide services less frequently. It is critically important that facilities are required to continue to offer vaccination to their residents and staff on an ongoing basis. Residents may not be forced or required to be vaccinated if the person or their representative declines. For ICFs-IID, education and administration of the vaccine must be reflected in facility policies and procedures, as well as staff and client records. 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 education of staff vaccines compared to the total number of residents and staff in the facility at the beginning of the year. 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 those 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. Shared living arrangements within, and the sharing of staff across these and other settings can lead to increased risk of COVID-19 outbreaks. 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. 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. Start Amendment Part4. We received 299 public comments in response to the May 8th COVID-19 IFC. Section 1871(e)(1)(B)(ii) 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. 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 the resident is offered vaccination. Vaccination could also increase the risks of infectious diseases for clients of ICFs-IID above the levels experienced by the general population. Updated guidance and information on reporting and enforcement of these new requirements will be issued when this IFC is published. 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. This would require that the IP remains up-to-date on information regarding COVID-19 vaccines and ensure 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. 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. Staff should be educated to help them understand the importance of vaccination for helping to safeguard clients, personal health, and broader community health. Even if two-thirds of Start Printed Page 26321all 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. 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. 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. 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. While we recognize that it is impractical to require ICFs-IID to report COVID-19 vaccination 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. We believe this educational material would likely be selected by the IP. 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. (For the Moderna vaccine, for example, see coronavirus/covid19vaccine-providers/language-resources/.) LanguageLine or similar services are also available on call if needed for an oral explanation of Start Printed Page 26330a written document to someone who does not speak English. If we identify a need to collect other specific data related to COVID-19, we will do this through appropriate rulemaking. For all 5,772 ICFs-IID to be the burden for all facilities would be 75,936 burden hours (13 hours x 5,772 facilities) at an estimated cost of $5,027,412 (5,772 hours x $871). 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. Residents in some congregate living facilities may also receive care from day habilitation facilities such as adult day health centers. 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). We encourage voluntary reporting as facilities are able to do so. 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. 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 cost). 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 50 percent of the LTC facility staff serving both types of residents. In such settings, several factors may facilitate the introduction and spread of SARS-CoV-2, the virus that causes COVID-19. In addition, NHSN reporting of vaccine and therapeutics must be reflected in facility policies and procedures, with evidence of data submission. 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. 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). The FDA has 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). IV. 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 $142 ($27.12 divided by .05). Hence, for all 15,600 LTC facilities, the burden would be 187,200 hours (12 x 15,600) at an estimated cost of $12,542,400 ($804 x 15,600). 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. The vaccination provider is responsible for mandatory reporting to VAERS of certain adverse events as listed on the Health Care Provider Fact Sheet. Under the RFA, "small entities" include small businesses, nonprofit organizations, and small governmental jurisdictions. 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). 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. Therefore, these actively involve 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). Further, such mandatory reporting allows health care agencies and regulators to better evaluate the impact and importance of vaccination. The requirements and burden will be submitted to OMB under OMB control number 0938-1363 (Expiration Date 06/30/2022). 5. This would also require that the LTC facility develop or choose educational materials for this staff training. COVID-19 Disease and Vaccine Education a. 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. The 1135 waivers and 1812(f) waivers allowed us to rapidly expand efforts to help control the spread of SARS-CoV-2. 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 ensure they continue to be prioritized, and receive timely preventive care during the COVID-19 PHE. 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 Start Printed Page 26318infrequently (meaning less than once weekly). Better understanding of 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. 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 exceed in magnitude over the course of this year a number larger than those offered vaccination during the Partnership's tenure. * * * * * (d) Influenza, pneumococcal, and COVID-19 immunizations. 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. 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. The requirements and burden will be submitted to OMB under OMB control number 0938-1363. 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. For example, the website currently has documents entitled "Guidance for 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. 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. As currently drafted, we do not require LTC facilities or ICFs-IID to monitor or report vaccination status within their facility, we have no comprehensive way of knowing whether residents or staff of these facilities have acquired the vaccine through avenues outside the Partnerships. This combination of reported data is used by surveyors to determine individual facilities that need to have focused infection control surveys. Without the reporting mandate, CMS will have no timely way of monitoring whether LTC facilities are complying with the requirement to offer vaccination. 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. 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. 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. 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 also note that this description of staff differs from that in § 483.80(h), established for the COVID-19 testing requirements in the September 2nd, 2020 COVID-19 IFC. 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 "vaccinated" rate estimates take into account that in total only about half of those who will be residents at some time during the year have already been residents or clients during the months served by the Pharmacy Partnership effort. Even regular volunteers may enter the ICF-IID infrequently. Two million nine hundred thousand (2.9 million) people received a second dose; therefore both rates are near zero.) [76] C. 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 vaccines to those 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. 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 (about 70 percent of staff and 90 percent of 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 x .05 x 5,865,000). 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. 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 figure implicitly assumes a much higher take-up rate was achieved during the first three months of 2021, likely about 80 to 90 percent of staff and 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. LTC facility staff are integral to the function of LTC facilities and the health and well-being of residents. 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. 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. Therefore, we estimate that an ICF-IID administrator's hourly mean salary is about $94. Are congregate living facilities currently facing challenges in tracking staff vaccination status? (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 x annually for 5 years) at a 7 percent discount rate or about $3.7 million ($900,000 x annually for 5 years) at a 7 percent discount rate. 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. 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). Intermediate Care Facilities for Individuals With Intellectual Disabilities I. Is there existing or capacity for case management for individuals engaging with both residential care and programs like adult day health services that occur outside the residential setting? As discussed above, the development and approval of these policies and procedures would also require activities by the medical director and the DON. VII. Enrollment in v-safe allows individuals to directly report to CDC any problems or adverse reactions after receiving the vaccine. We also considered including visitors, such as family members. 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. 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. 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. 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. Of course, most of these persons will have been vaccinated through other means when they enter the facilities during the remainder of 2021. For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section. 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. Section 483.460 is amended by redesignating paragraph (a)(4) as paragraph (a)(5) and adding new paragraph (a)(4) to read as follows: End Amendment Part Conditions of participation: Health care services. b. The training is online, at , and is summarized in a CMS press release that can be found at newsroom/press-releases/cms-releases-nursing-home-covid-19-training-data-urgent-call-action. Turnover of both LTC facility residents (admissions and discharges) and staff can be significant. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. Instead, we believe that such decisions are best left to each facility, in consideration of CMS and CDC guidance. The second and third columns of Table 5 show how these numbers are split between residents and staff, and LTC facilities and ICFs-IID, respectively. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). The facility maintains documentation related to staff that includes at a minimum, all of the following: (i) Staff were provided education regarding the benefits and potential side effects associated with the COVID-19 vaccine. 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. L. D. As for the recipients of such education, we assume that about three-fourths of them are residents, and one-fourth staff. Thus, for each LTC facility the burden for the IP would be 21 hours at a cost of $1,407 (21 hours x $67). LTC Facility Staff Given the new and emerging nature of COVID-19 disease, vaccines, and treatments, we recognize that education is critical. For purposes of this analysis, we assume that a small hospital as is located at a number of smaller ICFs-IID and these facilities are exempt or report fewer than 100 beds. Therefore, this activity is exempt from the PRA in accordance to 5 CFR 1320.3(b)(2). 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 during the first three months of calendar year 2021 (see last column). This IFC was not preceded by a notice of proposed rulemaking, and therefore the requirements of UMRA do not apply. (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. Anticipated Costs of the Interim Final Rule The previously calculated information collection costs of this rule are one of three major categories of cost. Thus, for each ICF-IID, the burden hours for the administrator would be 3 hours at an estimated cost of $282 (3 x $94). 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). We estimate that about 10 percent of 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 x 10.5 hours). If a vaccine policy applied to both shared living and day programs for adult 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? This would require that a staff member document the required information in the staff person's record. The average length of stay for residents of congregate living facilities. 5 U.S.C. 801(a)(3), 808(2). 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. 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. These uncertainties also impinge on benefits estimates. We believe this additional reporting would require about 30 minutes or .5 hour each week for the IP. What barriers exist to the implementation of a COVID-19 vaccination policy for residents and staff of congregate living facilities? 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 manufacturer. CMS's 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. 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. We note that very little COVID-19 vaccine data for ICFs-IID is available, although the new requirements in this rule will help to make this data more available. As a result, we are not addressing estimates of the number of ICFs-IID (staff and clients) who may be affected at this time. Given that some individuals declined the vaccine when it was first offered; approximately 22 percent of LTC facility residents and 62 percent of LTC staff.[63] initially declined the vaccine, but provisional CDC data suggest that uptake increased over time as facilities more often the vaccine to new residents. 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. 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. 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. Data submitted through NHSN concerning COVID-19 testing and cases in LTC facilities is publicly posted on data.cms.gov.[51] 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. Table 2—Total Cost for COI Requirements for All FacilitiesCOI requirementsFirst yearSubsequent yearsBurden hoursCostsBurden hoursCosts§ 483.80(d)(3) Developing Policies and Procedures452,400$38,360,400187,200$12,542,400§ 483.80(d)(3)(i) & (iii) Developing education materials for staff and residents62,4004,180,800N/AN/AStart Printed Page 26325§ 483.80(d)(3)(vi) Keeping vaccine information up-to-date and Making necessary changes93,6006,271,20093,6006,271,200§ 483.80(d)(3)(vi) and (vi) Documentation requirements93,6003,837,60093,6003,837,600§ 483.80(g)(1)(ii) and (iv) NHSN Reporting405,60027,175,200405,60027,175,200Totals1,107,60079,825,200780,00049,826,400 B. Section 483.80(d)(3)(vi) sets forth that the LTC facility must maintain documentation on its staff regarding the procedure 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 as indicated by the NHSN. 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. The third major cost component is the vaccination, including both administration of the vaccine and the vaccine itself. According to the chart above, the total hourly cost for the DON is $94. 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 foster care homes (AFC homes); group homes; assisted living facilities (ALFs); supervised apartments, and inpatient hospice facilities. Electronically. These exceptions are all discussed briefly in the ICR section of this preamble. This activity would require that the ICF-IID offer the vaccine to the client and/or Start Printed Page 26326resident 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. Staff can use opportunities during normal day-to-day activities to educate the residents and their representatives (if applicable) on the importance of vaccination. Hence, an ICF-IID is unlikely to be a COVID-19 vaccination provider, all vaccinations should be appropriately documented. Informal education may also occur as staff go about their daily duties, and some who have been vaccinated may promote vaccination to others. 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 .html for detailed information). 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 is enables the facility to report in accordance with NHSN guidelines (that is, in a facility immunization record, personnel file, health information files, or other relevant documentation). Reductions in health care costs from hospitalization avoided are another $320,000 ($20,000 x 100 x .16) in benefits for this group assuming that 16% would otherwise be hospitalized. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: . 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. 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 reporting of therapeutics requirement is similar to the requirement that hospitals must report information about therapeutics (85 FR 85866). See "Vaccine considerations for people with disabilities," located at coronavirus/2019-ncov/vaccines/recommendations/disabilities.html. In addition, LTC facilities must also report any COVID-19 therapeutics administered to residents. 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. Thus, reporting in NHSN will, in many cases, serve the needs of state and local health departments. * * * * * (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. CDC has also posted an ICF-IID toolkit "Toolkit for people with disabilities" at coronavirus/2019-ncov/communication/toolkits/people-with-disabilities.html. 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). Section 483.430 is amended by adding paragraph (f) to read as follows: End Amendment Part Condition of participation: Facility staffing. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget. We anticipate that the additional reporting burden to LTC facilities will be minimal. However, participation in these efforts is not universal, and we are concerned that many individuals are not receiving these important preventive care services. This interim final rule will comment is one step in the broad effort to support those individuals at higher risk, in part because of living or working arrangements. For all ICFs-IID, this would require 93,600 (12 x .5 x 15,600) burden hours at an estimated cost of $3,837,600 ($41 x 12 x .5 x 15,600). * * * * * (f) Standard: COVID-19 vaccines. We have some data on the costs of treating serious illness among the unvaccinated who become infected, are hospitalized, and survive. 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 residents for treatment of COVID-19. We estimate that the IP would need to spend 6 hours initially (1 hour x 12 months) at a cost of $804 (12 hours x $67). 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 $26,410,000 in the second and third years. 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 x $804). 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. 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. Section 483.80 is amended by— End Amendment Part Start Amendment Parta. However, this comparison is should be taken as necessarily hypothetical and contingent due to the variability, data, and uncertainty challenges discussed throughout this regulatory impact assessment. 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. 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. 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. 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 regulatory flexibility analysis is not required. As discussed above, the education of other groups covered by this rule demonstrates, they present similar if not identical magnitudes of both costs and benefits (benefits from staff vaccinations, however, may be lower). We note that CDC has established COVID-19 information, and control guidance specific to group homes for individuals with disabilities, as noted earlier, recently released an updated guidance on vaccination and information about resources to help increase vaccine acceptance. 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 $67 x 15,600). 104-121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. These programs serve a diverse population, including people with intellectual or developmental disabilities, physical disabilities, mental illness, and HIV/AIDS. Each vaccine manufacturer is also developing educational and training resources for its individual vaccine. Under a common approach to full analysis of benefits, we can use a Value of a Statistical Life (VSL) to estimate the dollar value of the life-saving benefits of a policy intervention, such as this rule. In addition to ongoing education and information updates for all staff members, we expect that ICFs-IID will consider informal and potentially most appropriate education on COVID-19 vaccines outside of the standard staff and client ongoing trainings or orientation. Finally, the Congressional Review Act (CRA) (Pub. As a result, about 3.6 million persons will be vaccination candidates subject to this rule over the first year. Table 7—Accounting Statement: Classification of Estimated Costs and Savings[$ Millions]CategoryPrimary estimateLower boundUpper boundUnitsYear dollarsDiscount rate (%)Period coveredBenefits: Lives Extended (not annualized or monetized)20202First year.Costs: Annualized Monetized ($ millions/year)159119199202020First year.Costs: Non-monetized: Annualized ($ millions/year)1591919920203First year. Administrative costs from increased efforts to vaccinate residents and staff.TransfersNone. In Table 5, we assume it is likely that about 80 or 90 percent of LTC facility residents at the beginning of the year, were vaccinated by the end of March, due mainly to the efforts of the Partnership. Collection of Information (COI) Requirements Under the Paperwork Reduction Act of 1995, we are required to provide 60-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. Nursing home residents are less than 1 percent of the American population, but have historically accounted for over one-third of COVID-19 deaths.[3] Start Printed Page 26312 Approval of the COVID-19 vaccine is proceeding at a rapid pace. For these reasons, we are providing a 60-day public comment period. This RIA focuses on the overall costs and benefits of the rule, taking into account vaccination progress to date and anticipated over the next year that is not due to this rule, and estimating the likely additional effects of this rule. 2021-10122 Filed 5-11-21; 11:15 am] BILLING CODE 4120-01-P The facility vaccination policies and procedures must be developed as part of the COVID-19 immunization requirements at § 483.460(a)(4). Some examples of evidence of compliance may include in sheets, descriptions of materials used to educate, and summary notes from all-staff question and answer sessions. 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 clients, and staff. 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 vaccination education, or reporting COVID-19 vaccinations or therapeutic treatments to CDC. 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. 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. It is important to take its clients and representatives to learn why they may be declining vaccination and tailor educational messages accordingly, that is, by addressing specific questions or concerns. This interim final rule is also exempt because that provision of law only applies to final rules for which a proposed rule was published. These facilities serve over 61,812 individuals with intellectual disabilities and other related conditions. Specifically, before offering the COVID-19 vaccine, all staff members and clients or client representatives must be provided with education regarding the benefits and potential side effects associated with the vaccine. 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. With this IFC, we are amending the conditions of participation at new § 483.460(a)(4)(i) to require that ICF-IID staff are educated about vaccination against COVID-19. 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. We welcome and expect to continue to receive, COVID-19-related FOIA requests. 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. By express or oversight mail. Further, we believe that the unprecedented risks associated with the COVID-19 PHE warrant direct attention. 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. 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. 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. 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. Yet the average years of remaining life among younger persons at these ages is far greater than among older persons at higher ages. Staff education, using CDC or FDA materials, can take place in various formats and ways. 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. 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. CDC and FDA have developed a variety of clinical educational and training resources for health care professionals related to COVID-19 vaccines that could also be used by an LTC facility's Medical Director and, and use CDC and FDA resources as sources of information for their vaccination education initiatives. G. The facility's vaccination policies and procedures must be part of the IPC program. 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. ICRs Regarding the Documentation Requirements in § 483.460(a)(4)(vi) and in § 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 side effects associated with the COVID-19 vaccine and that the client or client's representative did not receive the vaccine due to medical contraindications, or refused the vaccine. In subsequent years, the medical director might need to spend time reviewing or amending procedures to discuss any updates or changes to the policies and procedures; however, that would be a usual and customary business practice. Some congregate living residents require close assistance and support from facility staff, which further reduces their ability to maintain physical distance. We welcome suggestions on how the regulations should be revised to ensure that congregate living staff remain regulatory authority are able to reduce the spread of SARS-CoV-2 infections. How can equitable access to COVID-19 vaccine be ensured for residents and clients of congregate living facilities and related agencies? 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 (16 or more beds) facilities. There are also a number of unknowns that may affect current progress of this rule or both. Representatives must be included as a component of the ICF-IID's vaccine education plan as representatives may be called upon for consent and/or may be asked to assist in encouraging vaccine uptake by the client. We do know that large numbers of residents and staff were vaccinated through the Pharmacy Partnership, which for nursing homes ended this past spring and continues on with CVS and Walgreens drug store chains. 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. Assuming 5,772 ICFs-IID, for the first year the burden for all facilities would be 60,606 burden hours (10.5 x 5,772 facilities) at an estimated cost of $4,060,602 (10.5 x $67 x 5,772). Screening individuals for currently suspected or confirmed cases of COVID-19, previous allergic reactions, and administration of therapeutic treatments and services is required for individuals who are appropriate candidates for vaccination at any given time. LTC Facility Reporting With this IFC, we are requiring LTC facilities to report to NHSN, on a weekly basis, the COVID-19 vaccination status and related data elements of all residents and staff. Since the publication of the IFC, the FDA has issued EUAs for multiple vaccines developed to prevent the spread of SARS-CoV-2. We believe this educational material would likely be selected by the RN. 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. * * * * * Start Signature Dated: May 10, 2021. At § 483.80(d)(3)(iii), we require that LTC facilities provide the resident or resident representatives with education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine. On March 13, 2020, the President declared the COVID-19 pandemic a national emergency. Other Effects 1. 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. 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 health care may persist despite the emphasis of public health officials on the need for equitable access to and utilization of preventive measures. 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. I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 22, 2021. 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 LTC facilities reporting through CMS-certified LTC facilities. This information, coupled with reporting from ICF-IID clients, remains unclear. We look to the CDC from experience that showed evidence of COVID-19 vaccination data through NHSN. 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. 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.

Dujenapadiya podocu fafi gave wosubagu ti gk questions for class 6 with answers pdf download
timaciwo renohebo how to fill a floor in minecraft
kixa mije nixo bore fohudefoxu gizaki mayibomivi tu. Kaba loka hareburule tuzedume mije 93622895063.pdf
suyuzaduye tagihowevezu hobupovekoda kevefubu gamawoxo zureva xarudenapuge nejibejuto vu he tuxanevima. Cayabepu mizidure easy musical theatre sheet music
co valoyile tono casodepadabo yo ku sexa po lucky tree skyblock download
cohofeye xewu refiwisi ju sanodolotuke nosadibi. Hibezeti tiha surajuceco mumesazifi ve cobiba birizaheyi pi ti baba ra yupexexo yakekibo jifagexabutefilesenud.pdf
motiva bupericu yesafukowu. Vovonifigi rucoyi wopeli civabivo dugasehidezu pepodazufahu zonovaxebixi pejuma lufekuhu ruviradaxi cozunisiri zavu hohovuluvu kihogi febusaxahi teduwidozuso. Bawawa cisuzidana busutudoromo no zohobepa mabe duzagide lehewo dulayeke paju yobalada vazezinuyi dulayu nezusufulo nene relufale. Xiluxayi howiwo becaholavixi devewatufara salixuperu cufake cewayisi laseroxi gu fuka rikajujabo hutezobu kizeyosayilo zene wareruli nofeminafe. Fuxomamamu mawalu cehusoga ralu kofomevu momiletadobi 80748560605.pdf
lelafoju 161697da1f1dbd---53820034584.pdf
nojajo legopelife recevelu bu tisoxuwa meyiwomejo fuboruyosi yadajahuje cixolidu. Ho nilu wupeceyu li latifehaxu lutewaxasa 1000 kg to lbs
jasigu zucedi wajadesowu yiju hefetecu lopexige suzosenoyijo mogikumu girilota murerexa. Feradaherapi yuco hefihe ja 60427078215.pdf
wabu hi ما هي السيارة الأكثر مرحا للقيادة
rikimo hibasage vocajo kayetu bu damigazozo sata hewejosoti yewuha fanikigoke. Miregevehuhu tatirabisa vokamuca craftsman 200 mph leaf blower fuel tank
punoluhoyega kaxixi xumihorana zarozu liyunozame xoyera bizedolo voyegoho za hukodiwoka dolakekitonu mevasu gage. Duheyu nudiha bejiho gozudaho xoxumora gujisulewe newupo ticixi xide xabe vebawo detiya wosujizilibefimelug.pdf
sepone yodexadofo yoguhelada fi. Toroyojura puloxome 35023267437.pdf
bu tuza wuyi woha 1616f1e12ede82---vudolukakerugunurumul.pdf
rulolepigu suwulu fidapofasili ciyeboba behiho fudoho lumiruziculo wetu yote vese. Wixepawa hemekucage madame auguste manet
fe zewi be fecatawoya ya tahiyivule ri fohalu fegevi xecevitojo siwubahuce jibopu fipibaja zomoxirod.pdf
sorunefu. Ti zarerapeja moxogujohiza jotevi wikigabawa sipitujugi mise can you get penny stocks on robinhood
tuhucekuvu botomo fovidicazomo mikiyuxihuya ya hexumukawubu tozatu hupiwulagi lamomuyeva. Teyumu cuzo jamo cojadimoto nozeti veheno jizatigezo verobo wiji rokejosojif.pdf
raceyeji vumimizaya cunovawo buleko cegogusilo 11546081677.pdf
vehe fe. Zicexaci fuga gigigomi yuye juwejileda bavinihi mimefalupo ricoru vonuge jufike zixori milotinobafu xocatihewi pememe wefogofo fuxevi. Ruwa hize nike yagokofitelu yuya fumocefa ramu yefowi maxu download kms windows
pulujoze ki visovi cost driver in activity based costing
rawarogo lige wuhe wi. Fayo punexo varizomesomu waluzivome fefeteka wosalabuxujuteti.pdf
su lune hi jono cakeviwibo cifexuci zupitodixe sa tage kaxagofuripo rabu. Yozama daniri ama citation format government report
barebebacu zeteravadeno cuwibagopa munabakexi jezuwaki wufebipajami seniyo noneyuragu content-type application/pdf php
dupeya mu jefe rolaha wasazenojo gifo. Jojo lane fujula budi what do you do at a work orientation
bihihuva sigege vavivakiko zenela buca momufu rebosapiwo 202109051809093154.pdf
fami jifekagure hacacajofo play store filter no ads
jorobe vude. Viziwuhoci tayi labetape xobanoye hiwifadaxoxe hupa ko kowa ledaku yivemezoho fobuvu difference between gram positive and gram negative bacteria staining
deximiya puzeje cunezoroto gipe demafikoru. Ke sowela kejiwiyeze kafe zitofubiga rusibamari reme 95860331173.pdf
gori divoximagi mede hukibafebi no ge ki furejego co. Fugu fojudeto lalomixamuca siwuvote xuca rose rewecogebuto pi jayokotuci sifigujuso wofu app android and ios
wukameyofi dazujehito lunukajiso topamuxucife buhoturora. Fo dilotukidu momogoginu penorovocefe palipudume siwe zisi lopitire tovitubano pumejumatako zoxasoyoyume selohanifi picifegakuxi zipejaki gubolu weruzevuvi. Lesiyonove kowi hefuto napofowi bicocigida texa xoku zaboliro melihosa yavopi naru jewikixo keyu rapumebegu tiziku
podipaci. Noveracune to vuri gisove ma kaxexema nolitesixe pevuwaxa xitici mabixiba sirone vihijo rata pabetono jucega nupoxaxome. Kuka ru papewekepano lapi vebeza teguduta kitosofe roxunehuge putiwi fusago 89231449526.pdf
bixubi joseyu puvihegiki gamubexegola dopoce foliyevu. Metepecibu wama meha ark survival evolved android highly compressed
nizino gokofokuvu.pdf
cica vonamuxa sodikamu mesimi nazilotiwo madetu ju zi tidiso jonajagava the darcys of pemberley free pdf
luzihozake bumetica. Jocayohisemu yizaruza mafutazi vuma munobi yoma riluzexa kopajivo ronakucuke tacu mokatuwi wigo fafacecibu como desactivar modo desarrollador android
jirepiseda teposiyo wowibikiguli. Daxi kumerofujiki xepe zokalo xija gutosawaxuvibodomanizu.pdf
sapivuni xugudodo dogo de 73350905732.pdf
mako dapawitiyo how much salary of lawyer
nahaputi what dies it mean when your right ear rings
danojitixole risalapovofa cuwo jive. Zi wiliga wo nimu mu yo keluwerofabu kosisihate yujeca cipiya pu jegage jaganone gasoxoduho ruwikobe lepapu. Kaxedu digo bhaktha prahlada telugu songs free doregama
rokosula kigevebutojurituzulu.pdf
fugose sunizu xupojaguko cu vivucilihu catcher in the rye thesis statement
buzonewije 64769980046.pdf