

Supporting Statement – Part A

Conditions of Participation for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) (CMS-10777)

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of the Paperwork Reduction Act (PRA) requirements for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) for the COVID-19 Vaccine. ICFs-IID facilities are required to meet these requirements in order to participate in the Medicare and Medicaid Programs.

ICFs-IID are residential facilities that provide services for people with disabilities. There are currently 5,768 Medicare- and/or Medicaid-certified ICFs-IID, and all 50 States have at least one ICF-IID. The Social Security Act created this benefit to fund "institutions" (4 or more beds) for individuals with intellectual disabilities, and specifies that these institutions must provide "active treatment," as defined by the Secretary. This program serves over 66,000 individuals with intellectual disabilities and other related conditions. Most have other disabilities as well as intellectual disabilities. Many of the individuals are non-ambulatory, have seizure disorders, behavior problems, mental illness, visual or hearing impairments, or a combination of the above. All must qualify for Medicaid assistance

Currently, the Conditions of Participation: "Health Care Services" at 42 CFR 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. In order to help protect ICF-IID clients from COVID-19, CMS finalized a policy that required each ICF-IID facility to have a vaccination program that meets the educational and informational needs of each client, parent (if the client is a minor) or legal guardian, and staff member. The program should provide COVID-19 vaccines, when available, to all clients and staff who choose to receive them.

On May 13, 2021, CMS published an interim final rule with comment period (IFC), CMS-3414-IFC , entitled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff." (86 FR 26306) Based on the rule changes, we have reassessed the burden associated with certain information collection requirements (ICRs), as indicated below.

B. Justification

1. Need and Legal Basis

Section 1905(c) and (d) of the Social Security Act, gives the secretary authority to prescribe regulations for intermediate care facility services in facilities for individuals with intellectual disabilities or persons with related conditions.

Sections 483.400 – 483.480 are located in Part 483 of the Code of Federal Regulations, Subpart I- Conditions of Participation for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID). These CoPs establish the health and safety requirements that ICF/IID providers must meet in order to participate in the Medicare and Medicaid programs.

Individuals residing in congregate settings, regardless of health or medical conditions, are at greater risk of acquiring infections, and many clients of Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) face higher risk of severe illness due to age, disability, or underlying health conditions.

Currently, the United States (U.S.) is responding to a public health emergency of respiratory disease caused by a novel coronavirus that has now been detected in more than 190 countries internationally, all 50 States, the District of Columbia, and all U.S. territories. The virus has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2), and the disease it causes has been named “coronavirus disease 2019” (COVID-19). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a “Public Health Emergency of International Concern.” On January 31, 2020, pursuant to section 319 of the Public Health Service Act (PHSA) (42 U.S.C. 247d), the Secretary of the Department of Health and Human Services (Secretary) determined that a public health emergency (PHE) exists for the United States to aid the nation’s health care community in responding to COVID-19 (hereafter referred to as the PHE for COVID-19). On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, the President of the United States declared the COVID-19 pandemic a national emergency. The January 31, 2020 determination that a PHE for COVID-19 exists and has existed since January 27, 2020, lasted for 90 days, and was renewed on April 21, 2020; July 23, 2020; October 2, 2020; and January 7, 2021.

Given the new and emerging qualities of COVID-19 disease, vaccines, and treatments we recognize that education and offering of the vaccine to clients and staff is critical. The vaccine may be offered and provided directly by the ICF-IID or indirectly, such as through a local health department, pharmacy, or doctor’s office. Vaccines may be administered onsite or at other appropriate locations. Implementation of COVID-19 education and vaccination

programs in ICFs-IID will help protect clients and staff, allowing an eventual return to more normal routines, including timely preventive health care; family, caregiver and community visitors; and group and individual activities.

2. Information Users

Most of the ICRs contained in this regulation are designed to assure that ICF-IIDs have developed policies and procedures at to ensure that each client, client's representative and staff members are educated about the COVID-19 vaccine.

We are requiring ICF-IIDs offer, educate and document the COVID-19 vaccine to each staff member and client when the vaccination is available to the facility, unless the vaccine is medically contraindicated, the client has already been vaccinated, or the client or the client's representative has already refused the vaccine. These tasks are to be performed by the ICFs-IID administrator and a registered nurse on site.

We also require that the ICF-IID facility provide all of its staff with education regarding the benefits and potential risks associated with of the COVID-19 vaccine. The facility must document in client and staff records. We do not currently require the ICFs-IID to report any information to the NHSN at this time, but have recommended that voluntarily report the information to the NHSN.

3. Use of Information Technology

This information will not be collected electronically. ICFs-IID do not use electronic health records currently. The information will be documented in each client's medical record and staff members personnel record.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

Most ICF-IIDs are small entities because they are either non-profit organizations or meet the small business administration definition of a small business. We estimate that the average annual costs per client in an ICF-IID is \$140,000. Since nearly all of these costs will be reimbursed through the CARES Act or other COVID-19 funding sources, the financial strain on these facilities should be negligible and the likely net effect positive.

Considering the cost savings from treating seriously ill residents, the financial impact is likely to be positive. Therefore, these requirements will not have a significant economic impact on a

substantial number of these small entities.

6. Less Frequent Collection

CMS does not collect this information directly from ICFs-IID on a scheduled basis. Facilities are expected to collect and maintain their own records in a timely fashion and to be able to provide necessary records to State or Federal surveyors when needed to demonstrate compliance with the ICFs-IID requirements for participation. With less frequent collection, CMS would not be able to assess or ensure compliance with the requirements.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A 60-day *Federal Register* notice of the “Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff.” (RIN 0938-AU57, CMS-3414-IFC published on May 13, 2021 (86 FR 26306).

9. Payments/Gifts to Respondents

There will not be any payment or gifts provided to respondents.

10. Confidentiality

Confidentiality of this information is assured since all information is kept in personal records.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

In analyzing PRA costs, we rely heavily on wage and salary information. Unless otherwise indicated, we obtained all salary information from the May 2019 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS) at https://www.bls.gov/oes/current/oes_stru.htm https://www.bls.gov/oes/current/oes_nat.htm. Furthermore, where applicable, the wage information for each occupation were pulled from the BLS industry category “Long term care facilities.” Based on this information, we have calculated the estimated hourly rates for the ICFs-IID requirements in this proposed rule based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from the BLS

does not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs.

Table 1: Total Hourly Costs by Position

Position	Mean Hourly Wage	Total Cost
ICF-IID: RN	\$33.53 ¹	\$67
ICF-IID: Administrator	\$46.78 ²	\$94

1. §483.460 Condition of participation: Health care services.

§483.460(a)(4) Policies and Procedures

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

¹ Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 29-1141 Registered Nurses. Accessed at <https://www.bls.gov/oes/current/oes291141.htm>. Accessed on March 18, 2021.

² Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 11-9111 Medical and Health Services Managers. Nursing Care Facilities (Skilled Nursing Facilities). Accessed at <https://www.bls.gov/oes/current/oes119111.htm>. Accessed on February 17, 2021.

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

For the ICF-IID administrator, we believe it would require 3 hours for him or her to work with the RN in developing the policies and procedures and give final approval before taking the policies and procedures to the governing body for approval. We believe that he or she would likely make a salary similar to that of a manager in the LTC setting, like that for the Director of Nursing (DON) salary as discussed above. Therefore, we estimate that an ICF-IID administrator's hourly mean salary is about \$94. Thus, for each ICF-IID, the burden hours for the administrator would be 3 hours at an estimated cost of \$282 (3 hours x \$94). For all 5,772 ICFs-IID, the total burden for the administrator would be 17,316 hours (3 hours x 5,772 facilities) at an estimated cost of \$1,627,704 (17,316 hours X \$94).

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

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

§483.460(a)(4)(ii), (iii), and (iv) Education Requirements for Staff and Clients

At new §483.460(a)(4)(ii), we require that the ICF-IID provide all of its staff with education regarding the benefits and potential risks associated with of the COVID-19 vaccine. New §483.460(a)(4)(iii) requires that the ICF-IID to provide each client or the client's representative education regarding the benefits and risks and potential side effects associated with the vaccine. In addition, new §483.460(a)(4)(iv) requires that the ICF-IID, in situations where

there are additional doses of the COVID-19 vaccine that was administered, a booster, or any other vaccine needs to be administered, must provide the client, client's representative, and staff member with the current information regarding the benefits and risks and potential side effects for that vaccine, before the facility requests consent for administration of that dose. We believe that all of the education provided by the ICF-IID to the client, client's representative and the staff would be virtually identical.

For the initial education, the ICF-IID would be required to develop educational materials by reviewing available resources on COVID-19 vaccines. We expect that most if not all ICFs-IID will use resources developed by other entities as there is a considerable amount of free information on COVID-19 and its vaccines available online. For example, CDC and FDA provide information on the COVID-19 vaccines online.^{3, 4} Finally, we expect that trade publications and other public sources would provide training materials. We believe this educational material would likely be selected by the RN. The RN would need to review the information available on the vaccines, determine what information needs to be presented to the client, client's representative and staff members, and gather that information as appropriate. An ICF-IID administrator would likely work with the RN and need to approve the final educational material. We estimate that it would initially require 7 hours and thereafter 6 hours annually to review for updates and make those changes to the educational materials for a total of 13 hours for the RN to accomplish these tasks in the first year. Thus, for each ICF-IID, the burden for the RN would require 13 burden hours at an estimated cost of \$871 (13 hours x \$67). For all 5,772 ICFs-IID so the burden for all facilities would be 75,036 burden hours (13 hours X 5,772 facilities) at an estimated cost of \$5,027,412 (75,036 hours x \$67).

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

483.460(f) Documentation Requirements for Staff and Clients

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

3 See FN#71.

4 See FN#72.

annually (0.25 x 12) at an estimated cost of \$123 (\$41 x 3 hours). For all ICFs-IID, the documentation requirements would be 17,316 burden hours (3 hours x 5,772 facilities) at an estimated cost of \$709,956 annually (17,316 hours x \$41).

Total Burden for Information Collections in §483.460

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

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 the second and third years. The annual burden hours are 114,478 (170,274 + 86,580 + 86,580/3 years). The annual costs are \$7,375,654.

13. Capital Costs

There are no capital costs associated with the information collection requirements.

14. Cost to Federal Government

The Federal government will sustain a burden from implementing and enforcing the final rule. Specifically, CMS will need to update the interpretive guidance, update the survey process, and make IT systems changes. We anticipate the majority of the system costs will be incurred between FY20 and FY21. In the final rule, we estimated initial federal start-up costs between \$15 and \$20 million. Once implemented, improved surveys to review the new requirements were anticipated to require an estimated \$15 to \$20 million annually in federal costs.

15. Changes to Burden

This is a new information collection requirement.

16. Publication/Tabulation Dates

There are no plans to publish the information.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date.

18. Certification Statement

We have not identified any exceptions.