

Supporting Statement – Part A

Conditions of Participation for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) (OMB Control Number 0938-1402)/(CMS-10777)

A. Background

The purpose of this package is to request from the Office of Management and Budget (OMB) the approval to reinstate, with change, the information collection request associated for OMB Control Number 0938-1402, titled “Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Conditions of Participation.”

The regulations containing the information collection requirements are located at 42 CFR Part 483 of the Code of Federal Regulations, Subpart I.

This is a reinstatement of the information collection request that expired on September 30, 2024. The previous iteration of this OMB Control Number 0938-1402 (approved September 22, 2021) had an annual burden of 114,478 hours and annual costs of \$7,375,654. For this requested reinstatement, with changes, the total annual burden hours for industry is **75,721 hours** and the annual burden costs are **\$5,470,418**. See **Section 15** below regarding the reasons for the changes in burden.

During the COVID-19 Public Health Emergency (PHE), individuals residing in congregate settings, such as ICFs-IID and Long-Term Care (LTC) facilities were at greater risk of acquiring COVID-19 infections and once infected, were at greater risk of severe illness or death. As a result, the Centers for Medicare and Medicaid Services (CMS) revised the Conditions of Participation (CoPs) for many of CMS’ certified providers including hospitals and institutional care settings in order to reduce the risk of exposure to and the severity from contracting the COVID-19 virus for medical and non-medical staff and patients. In addition to the CoPs, health care facilities were obligated to establish an infection control program that would protect the health and safety of residents, personnel, and the general public under Sections 1819(d)(3)(B) and 1919(d)(3) of the Act.

Individuals housed at ICFs-IID facilities are mentally and intellectually impaired, receive Medicaid assistance, and live in congregate settings. ICF-IID clients may also have other underlying medical conditions such as visual or hearing impairments, or seizure disorder.¹ Based on their living situation and underlying health conditions, these clients were at higher risk of exposure and severe consequences from COVID-19 and continue to be at higher risk due to new variants of COVID-19 and other similar acute respiratory illnesses.

¹ The appropriate term for an individual receiving care and services varies by provider. Most providers use the term “patients,” but LTC facilities use the term “residents” and ICF IID facilities use the term “clients.”

In the interim final rule, 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 (CMS-3414-IFC), that was published on May 13, 2021 (hereinafter “[May 2021 Interim Final Rule](#)”), CMS added new CoPs which required ICF/IIDs facilities to: 1) develop policies and procedures to educate clients, their representatives, and staff on the benefits and risks, and potential side effects of the COVID-19 vaccine; 2) educate and offer the COVID-19 vaccine per the policy and procedures developed; 3) document that staff and clients were educated and offered the vaccine; and 4) document whether or not a client or staff member received the vaccine and if not, if it was due to medical contraindications or refusal.² The [May 2021 Interim Final rule](#) included an estimate for the burden hours and costs to industry associated with these specific information collection requests and which was subsequently submitted to OMB as the initial PRA package for this information collection request in 2021.

In November 2021, CMS issued “[Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination](#),” 86 FR 61555 (CMS-3415-IFC) (hereinafter “[November 2021 Interim Final Rule](#)”), which mandated health care staff in all CMS certified facilities, including ICFs-IID, to be vaccinated.³ Most significantly, health care staff were no longer permitted to refuse being vaccinated and had to request an exemption if they did not want to receive the COVID-19 vaccine.⁴ As a result, ICFs-IID had to document that their staff were educated and offered the vaccine, and also document whether their staff received a vaccination or were approved for an exemption. Clients of ICFs-IID, however, were still allowed to refuse taking the vaccine which would be documented in their medical record.

On June 5, 2023, CMS issued a final rule, “[Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care \(LTC\) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities \(ICFs-IID\) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing](#),” 88 FR 36485 (CMS-3415-F, 3414-F, and 3401-F) (hereinafter “[June 2023 Final Rule](#)”), which eliminated the vaccine mandate on health care staff and finalized the CoPs related to the “educate and offer” activity for COVID-19 vaccines in LTCs and ICF-IID.⁵ Currently, ICFs-IID must continue to

² [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, 26317-26319 (May 13, 2021).

³ [Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination](#), 86 FR 61555, 61620 (November 5, 2021)

⁴ [Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination](#), 86 FR 61555, 61570-72 (November 5, 2021)

⁵ [Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care \(LTC\) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities \(ICFs-IID\) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements](#), 88 FR 36485, 36499-36500 (June 5, 2023)

educate on the risks and benefits of the COVID vaccine and offer the vaccine to clients and staff and must continue to document this activity for clients in their medical records. However, when the [June 2023 Final Rule](#) removed the staff vaccine mandate by eliminating the CoPs at 483.430(f) in its entirety, documentation of the educate and offer activity for staff was also eliminated. Thus, ICFs-IID must continue to “educate and offer” the COVID-19 vaccine to both staff and clients, but the current CoPs require facilities to document this task only for their clients. Although the COVID-19 PHE ended in May 2023, the COVID-19 related CoPs for ICF-IID as updated in the [June 2023 Final Rule](#) remain in effect post-PHE in order to protect clients and staff from the same risks as before that may be due to new COVID-19 variants.⁶

This reinstatement estimates the new burden hours for ICFs-IID based on the revised CoPs. The burden of the information collections for LTC facilities is included in **OMB Control Number 0938-1363**.

For a summary of the annual burden hours and costs for specific CoPs in this reinstatement see **Table 7**.

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.

ICFs-IID are residential facilities that provide services for people with disabilities. There are currently 5,523 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 64,000 individuals with intellectual disabilities and other related conditions.⁷

⁶ <https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html>

⁷ Based on ICFs-IID client population total of 64,812 provided in [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, 26308 (May 13, 2021).

Statutory requirements and our responsibility to assure an adequate level of patient health and safety in participating ICFs-IID require the inclusion of these requirements in the CoPs. We note that the ICRs contained within the regulations are necessary safeguards against potential overpayments, excessive utilization, and poor health care that may occur in the absence of such requirements. Therefore, we believe many of the requirements will impose no burden since a prudent institution would self-impose them in the ordinary course of business. Nonetheless, we have made an attempt to estimate the associated burden for an ICF-IID to engage in these standard industry practices.

2. Information Users

In general, the Conditions of Participation (CoPs) are used by Federal (CMS) or State surveyors (employed by State survey agencies) as a basis for determining whether an ICF-IID qualifies for approval or re-approval under Medicare. Surveyors make an in-person visit to ICF-IID to perform the complete survey.

3. Improved Information Technology

ICFs-IID may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR § 485.638. This regulation does not specify how the facility should prepare or maintain these records. Facilities are free to take advantage of any technological advances that they find appropriate to meet their needs.

4. Duplication of Similar Information

These requirements are specified in a way that does not require an ICF-IID to duplicate its efforts. If a facility already maintains these general records, regardless of format, these requirements are met. The general nature of these requirements makes variations in the substance and format of these records acceptable from one facility to another.

5. Small Businesses

These requirements do affect small businesses because most ICF-IIDs are either non-profit organizations or meet the U.S. Small Business Administration definition of a small business. However, the general nature of the requirements allows facilities the flexibility to meet the requirements in ways that are consistent with their existing operations.

6. Less Frequent Collection

CMS does not collect information directly from ICFs-IID and instead relies on State surveyors (employed by State survey agencies) to review the collection of information at the time of their certification and at the time of their facility visit. Nor does the rule prescribe the manner, timing, or frequency of the records or information that must be available. Facility records, policies, and procedures are reviewed at the time of a survey for initial or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare Conditions for Participation (CoPs), which in turn, would jeopardize the health and safety of ICF-IID clients and staff and provision of quality healthcare.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on January 14, 2025 (90 FR 3220). There were no public comments received.

The 30-day Federal Register notice published June 17, 2025 (90 FR 25616).

9. Payments/Gifts to Respondents

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

10. Confidentiality

Confidentiality will be maintained to the extent provided by law. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. § 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Requirements of HIPAA's Privacy Rules (at 45 CFR §§ 160 and 164) protect the privacy and security of an individual's protected health information.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Assumptions

Facilities Impacted

For the Calendar Year 2023, there were 5,523 active ICFs-IID and 24 newly certified facilities. For purposes of this information collection, we assume the number of terminated facilities per year is the same as the number of newly certified facilities, thus the total number of ICFs-IID facilities remains the same over the next 3 years.

Table 1: Facility Summary

Number of ICF-IID Facilities⁸	Calendar Year 2023
Total Providers	5,523
Hospital Based	11
Freestanding	5,512
Newly certified/year	24

Salary Data

Salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS) [May 2023 OEWS Industry-Specific Occupational Employment and Wage Estimates for Residential Intellectual and Developmental Disability Facilities \(NAICS 623210\)](#).

Where we were able to identify positions linked to specific positions, we used that compensation information. However, in some instances, we have used a general position description or information for comparable positions. We calculated the estimated hourly rates based upon the mean salary for that particular position, including fringe benefits and overhead estimated at 100 percent of the base salary, and rounded the numbers up to the next dollar amount where appropriate.⁹ The salary estimates (including estimated fringe benefits and overhead at 100%) contained in this package are based on the following healthcare personnel:

“**Administrator**” refers to the BLS Industry-Specific estimate for Medical and Health Service Managers (11-9111). The mean wage is \$36.98 per hour. For purposes of this ICR, we use the figure \$74 per hour, representing the mean wage plus fringe benefits and overhead.

⁸ Source: CASPER (08/11/2024), accessed via S&C's Quality, Certification and Oversight Reports (QCOR) at https://qcor.cms.gov/index_new.jsp

⁹ If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar.

“**Registered Nurse/RN**” refers to the BLS Industry-Specific estimate for a Registered Nurse (29-1141). The median wage is \$36.22 per hour. For purposes of this ICR, we use the figure \$72 per hour, representing the mean wage plus fringe benefits and overhead.

Table 2: Wage Summary

Personnel	BLS Labor Code	Mean Hourly Wage	Mean Hourly Wage w/Benefits
Administrator	11-9111	\$36.98	\$74
Registered Nurse/RN	29-1141	\$36.22	\$72

§483.460 Condition of participation: Health care services.

IC-1: §483.460(a)(4) – CoP: One time development of policies and procedures for “Educate and Offer” CoP

As discussed in detail above, Section 483.460(a)(4) requires ICFs-IID to develop policies and procedures to ensure that every client (or client’s representative) and staff member are educated about the COVID-19 vaccine before offering them the vaccine (or multiple doses).

We estimate the one-time burden of developing policies and procedures for both *existing* ICF-IID facilities and for *newly certified* facilities per year. We estimate a Registered Nurse (hereinafter “RN”) at an ICF-IID facility would spend 5 hours to research and write the initial draft of the policies and procedures. We estimate an ICF-IID Administrator would spend 3 hours to assist the RN create the policies and procedures and approve the initial policies and procedures for how the staff would comply with the requirements to educate and offer vaccinations to staff and clients. If additional time is needed by the Administrator to seek review and approval of the initial policy, such as with medical staff or the governing board, that effort should be considered as part of the usual and customary practice of operating an ICF-IID facility and thus would be exempt from the PRA in accordance with 5 CFR §1320.3(b)(2). Time spent to review and update the policy after its initial development and implementation is captured as an annual, ongoing burden below as a separate information collection.

Table 3: IC-1:One-time development of policies & procedures

Task	Hourly Mean Wage	Hours/ Task	Cost/ Task
One-time development of policies			
Administrator	\$74	3.0	\$222
Registered Nurse/RN	\$72	5.0	\$360
Total Task/Facility		8.0	\$582
Existing Facilities	5,523	44,184	\$3,214,386
Newly Certified Facilities	24	192	\$13,968
Total Annual Burden/Costs		44,376	\$3,228,354

According to Table 2 above, the total loaded hourly cost for an RN is \$72 and for an Administrator at an ICF-IID is \$74. Thus, for each ICF-IID, the burden hours for developing policies related to this CoP for the RN would be 5 hours at an estimated cost of \$360 (5 hours x \$72/hour) and for the Administrator would be 3 hours at an estimated costs of \$222 (3 hours x \$74), for a total of 8 hours at an estimated cost of \$582 per facility. For the initial year for all 5,523 ICFs-IID, the one-time burden hours would be 44,184 (5,523 x 8 hours) at an estimated cost of \$3,214,386 (5,523 facilities x \$582 per facility). In Years 2 and 3, assuming 24 newly certified facilities each year per Table 1, the total annual burden hours would be 192 (24 new facilities x 8.0 hours) at an estimated cost of \$13,968 (24 new facilities x \$582) for the one-time development of new policies each year.

IC-2: §483.460(a)(4) - Annual update of policies

Once the policies and procedures to “educate and offer” vaccines to staff and client per Section 483.460(a)(4) are created, we estimate an RN at each ICF-IID facility would spend 6 hours per year (or 30 minutes per month for 12 months) to review, revise or update the policies as needed. We assume the RN could update the policies each year without the need for Administrator approval, and if approval was needed, that effort would fall under the Administrator’s usual and customary duties and be exempt from the PRA in accordance with 5 CFR §1320.3(b)(2).

According to Table 1 above, the total loaded hourly cost for an RN is \$72. We estimate that for each ICF-IID, the burden to annual update the policies would be 6 hours for an RN at an estimated cost of \$432 (\$72 x 6 hours). For all 5,523 ICFs-IID, the annual burden hours would be 33,138 (5,523 facilities x 6 hours) at an estimated cost of \$2,385,936 (5,523 facilities x \$432 per facility).

Table 4: IC-2: Annual update of policies & procedures

Task	Hourly Mean Wage	Hours/ Task	Cost/ Task
Registered Nurse/RN	\$72	6.0	\$432
# of Facilities Impacted	5,523		
Total Annual Burden/Costs		33,138	\$2,385,936

IC-3: §483.460(a)(4)(ii), (iii), and (iv) - One time development of educational materials for staff and clients

As finalized in the [June 2023 Final Rule](#), the CoPs require ICFs-IID to educate their staff (§483.460(a)(4)(ii)) and their clients (or the client’s representative) ((§483.460(a)(4)(iii)) about the benefits and potential risks of taking or refusing to take the COVID-19 vaccine prior to being offered the vaccine.¹⁰ ICFs-IID must also educate staff and clients about the benefits and risks of taking additional doses of the COVID-19 vaccine prior to offering them to staff and clients per Section 483.460(a)(4)(iv).

In order to provide this education to staff and clients, the ICF-IID must first compile or create the educational materials that will be used to explain the risks and benefits. We assume each ICF-IID would tailor its educational materials based on the local and state laws of where the facility is located and the primary languages of clients or client representatives with Limited English Proficiency (LEP) per Title VI of the Civil Rights Act. In addition, the educational materials used must comply with all accessibility standards, such as Section 504 of the Rehabilitation Act. For example, the educational materials may need to be in braille or large print for those who are visually-impaired or in American Sign Language for those who are hearing-impaired.¹¹ We also assume each ICF-IID could use existing, accessible educational materials created by trusted resources such as the CDC or FDA and the materials used to educate clients could also be used to educate staff.

Based on these assumptions, we determine the one-time burden of developing the materials need to educate staff and clients about the benefits and potential risks of the required vaccines for both *existing and newly certified* facilities below. We estimate that compiling and or creating the

¹⁰ [Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care \(LTC\) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities \(ICFs-IID\) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements](#), 88 FR 36485 (June 5, 2023).

¹¹ [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, 26319 (May 13, 2021)(stating “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.”).

required education materials as discussed above would initially take 7 hours for an RN at each ICF-IID facility.¹²

Table 5: IC-3: One-time development of educational materials

Task per Facility	Hourly Mean Wage	Hours/Task	Cost/Task
Registered Nurse/RN	\$72	7.0	\$504

Task for all Facilities	Hourly Mean Wage	Hours/Task	Cost/Task
# of Facilities Impacted			
Existing Facilities	5,523	38,661	\$2,783,592
Newly Certified Facilities	24	168	\$12,096
Total Annual Burden/Costs		38,829	\$2,795,688

For each ICF-IID, the one-time burden hours for developing educational materials for the RN would be 7 hours at an estimated cost of \$504 (7 hours x \$72/hour). For the initial year for all 5,523 ICFs-IID, the one-time burden hours would be 38,661 (5,523 x 7 hours) at an estimated cost of \$2,783,592 (5,523 facilities x \$504 per facility). In Years 2 and 3, assuming 24 newly certified facilities each year per Table 1, the total annual burden hours would be 168 (24 new facilities x 7 hours) at an estimated cost of \$12,096 (24 new facilities x \$504 per facility) for the one-time development of educational materials each year.

IC-4: §483.460(a)(4)(ii), (iii), and (iv) – Annual update of educational materials for staff and clients

We estimate the additional burden to annually update the educational materials used to ensure the information provided is accurate and specific to the current vaccines available that year. We estimate it would take an RN at each facility 6 hours each year to review and update the educational materials on an ongoing basis. In addition, we estimate an ICF-IID Administrator would need 1 hour each year to review and approve the updated materials before the materials were provided to staff and clients.

¹² The prior package estimated for IC-3 that the RN would spend 13 hours in the first year to initially create the educational materials (7 hours) and to update the materials that first year (6 hours) on top of 6 hours for all facilities to annually update the materials. To avoid double counting the hours for the annual update in Year 1, the initial development of the materials and the annual update are considered two separate events.

Table 6: IC-4:Annual update of educational materials

Task	Hourly Mean Wage	Hours/Task	Cost/Task
Registered Nurse/RN	\$72	6.0	\$432
Administrator	\$74	1.0	\$74
Total Task/Facility		7.0	\$506
# of Facilities Impacted	5,523		
Total Annual Burden/Costs		38,661	\$2,794,638

For each ICF-IID, the burden hours for updating the educational materials each year would be 6 hours for an RN at an estimated cost of \$432 (5 hours x \$72/hour) and would be 1 hour for an Administrator at an estimated costs of \$74 (1 hour x \$74), for a total of 7 hours at an estimated cost of \$506 per facility. For all 5,523 ICFs-IID, the annual burden hours to update educational materials would be 38,661 (5,523 facilities x 7 hours) at an estimated cost of \$2,794,638 (5,523 facilities x \$506 per facility).

Documenting compliance with the “Educate and Offer” CoP

483.460(a)(4)(vi) – Client’s Medical Record documentation

The [May 2021 Interim Final Rule](#) added a new CoP at Section 483.460(a)(4)(vi) that required ICFs-IID to document in the client’s medical record that: 1) the client (or client’s representative) was educated about the benefits and potential risks of the COVID-19; 2) details about each COVID-19 vaccine the client received or 3) if the client did not receive a vaccine, whether it was due to the client’s refusal or “medical contraindications.”¹³ This CoP remained unchanged and was made final in the [June 2023 Final Rule](#).¹⁴ This documentation is directly related to the treatment and procedures provided to the client at the facility and would occur regardless of the CoP requirement. As a result, the burden of documenting the client’s vaccine status should be considered usual and customary practice by a health facility and be exempt from the PRA in accordance with 5 CFR §1320.3(b)(2).¹⁵

483.430(f) - Staff Documentation

¹³ [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, 26326 (May 13, 2021).

¹⁴ [Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care \(LTC\) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities \(ICFs-IID\) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements](#), 88 FR 36485, 36503 (June 5, 2023)(stating “ICFs-IID must continue to educate clients, client representatives, and staff and offer the COVID–19 vaccine to clients and staff, as well as perform the appropriate documentation for these activities.”).

¹⁵ The burden from this CoP was also deemed exempt from the PRA as usual and customary business practice per 5 CFR §1320.3(b)(2) in the [May 2021 Interim Final Rule](#) at 86 FR 26306, 26326.

The [May 2021 Interim Final Rule](#) added a new CoP at Section 483.430(f) that required ICFs-IID to “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.”¹⁶ The prior package included this activity as an information collection request that was subject to the PRA.¹⁷

The [November 2021 Interim Final Rule](#) substantially expanded the staff documentation CoP at Section 483.430(f)(iv) – (f)(ix) for ICFs-IID to include the vaccine status of staff members, staff exemptions (that had to be signed by a second practitioner), or if they had medical reasons for not getting vaccinated.¹⁸ Analysis of the burden of this expanded information collection request was included in the November 2021 rule at 86 FR 61555, 61593 and estimated the annual burden hours to be 6,664 at a cost of \$459,816 for 5,780 ICF-IID facilities.¹⁹

For reasons detailed in the preamble of the rule, the [June 2023 Final Rule](#) eliminated Section 483.430(f) in its entirety.²⁰ This included Sections 483.430(f)(iv) – (f)(ix) which detailed what facilities needed to document after staff were educated and offered the vaccine. Although CMS may have intended to continue requiring ICFs-IID to document when staff are educated and offered vaccines, as evidenced by language in the preamble, Section 483.460(a)(4)(v) - which only explains what documentation is required for ICFs-IID’ clients – has not been amended to include the term “staff” or “staff members.”²¹ As a result, there currently is no CoP that requires ICFs-IID to document if staff members were educated and offered the COVID-19 vaccine or their vaccine status.²²

¹⁶ [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, 26326 (May 13, 2021).

¹⁷ The prior package applied the same assumptions used in the [May 2021 Interim Final Rule](#) and estimated 17,316 burden hours and a burden cost of \$709,956 for 5,772 ICF IID facilities for this staff documentation requirement. Note the prior package incorrectly labeled this CoP as §483.460(f) instead of §483.430(f).

¹⁸ [Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination](#), 86 FR 61555, 61620-21 (November 5, 2021).

¹⁹ The burden assumptions included the task for staff documentation for every staff member would be 5 minutes (or .0833 hours) for an RN (at an hourly rate of \$69) and that there were 80,000 staff members at 5,780 ICF-IID facilities.

²⁰ [Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care \(LTC\) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities \(ICFs-IID\) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements](#), 88 FR 36485, 36486-87 (June 5, 2023)(stating “CMS intends to encourage ongoing COVID–19 vaccination through its quality reporting and value-based incentive programs in the near future” and is “now aligning our approach with those for other infectious diseases, specifically influenza.”)

²¹ The [June 2023 Final Rule](#) preamble states at 88 FR 36485, 36492 that “we [CMS] are finalizing the requirements for COVID–19 vaccination of *facility staff* and “educate and offer” process that ICFs–IID must meet to participate in the Medicare and Medicaid programs, as first set out in the educate and offer IFC [May 2021 Interim Final Rule] and *amended by the staff vaccination* IFC [November 2021 Interim Final Rule.” (emphasis added). In addition, the preamble at 88 FR 36485, 36503 states that ICFs-IID must “continue to educate clients, client representatives, *and staff* and offer the COVID–19 vaccine to clients *and staff, as well as perform the appropriate documentation for these activities.*” (emphasis added).

²² See all relevant CoPs for ICFs-IID at 42 CFR Part 483 Subpart I (2024).

Because the previous information collection request at 42 CFR §483.430(f) no longer exists and the requirement was not added elsewhere as a CoP, there currently is no burden on ICFs-IID to document the “educate and offer” activity for staff that is subject to the PRA.

Table 7 below provides a summary of the information collections burden hours and costs within this package. In total, we estimate that the information collection burden for all ICFs-IID would be 155,004 hours and \$11,204,616. Annualized over three years, the annual burden hours are **75,721** and annual burden costs are **\$5,470,418**.

Table 7: Total Annual Burden Hours and Costs to Industry

Information Collection No.	Responses	Respondents	Annual Burden Hours	Annual Burden Costs
IC-1: 483.460(a)(4) - One time development of policies	1	5,523	44,376	\$3,228,354
IC-2: 483.460(a)(4) - Annual update of policies	1	5,523	33,138	\$2,385,936
IC-3: 483.460(a)(4)(ii), (iii), and (iv) - One time development of educational materials	1	5,523	38,829	\$2,795,688
IC-4: 483.460(a)(4)(ii), (iii), and (iv) - Annual update of educational materials	1	5,523	38,661	\$2,794,638
Total Burden Hours and Costs to Industry			155,004	\$11,204,616
Burden Hours Annualized over Three Years				
Year 1 (IC 1 & IC 3 - Existing Facilities)	1	5,523	82,845	\$5,997,978
Year 2 (IC 1 & IC 3 - New Facilities and IC 2 & IC 4 - All Facilities)	1	5,523	72,159	\$5,206,638
Year 3 (IC 1 & IC 3 - New Facilities and IC 2 & IC 4 - All Facilities)	1	5,523	72,159	\$5,206,638
3 Year Total			227,163	\$16,411,254
Annualized Burden Hours and Costs to Industry over 3 years			75,721	\$5,470,418

13. Capital Costs

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

14. Cost to Federal Government

Sections 1905(c) and (d) of the Social Security Act provide for the use of State survey agencies to ascertain whether Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) comply with the applicable statutory definitions and implementing regulations for that provider or supplier type. The burden and costs to the federal government for this ICR are estimated to include the time spent by CMS State Surveyors to complete CoP compliance evaluations for ICFs-IID. There are multiple points in time when CMS conducts

evaluations of certified facilities for compliance with CoPs. First, each facility undergoes a CMS compliance review at the time of initial application for Medicare approval. Subsequent surveys for every hospital are conducted an average of every 4.5 years, but it varies between 3 and 6 years.

Cost to Perform Survey

The burden for completing these responsibilities was calculated using a loaded hourly median wage of \$91 per hour (including benefits) for a CMS State Surveyor, based on the BLS Industry-Specific estimate for “Compliance Officer – Federal/State Government” (13-1041).²³ For the initial compliance review, we estimate the cost to the Federal government to ensure each facility’s compliance to be 4 hours, with a net cost of \$364 per facility (4 hours x \$91). For ongoing compliance, we estimate the cost to the Federal government to ensure each facility’s compliance to be 1 hour, with a net cost of \$91 per facility (1 hour x \$91). The burden to the Federal government for each applicable information collection (IC) is calculated below with only those facilities that are impacted by each IC.

For this reinstatement, the total annual burden hours to the federal government is 55,422 with an annual cost of \$5,043,402. Assuming an FTE is 1,920 hours per year then we estimate there would be 29 FTEs ($55,422 / 1,920 = 29$ FTEs).

Table 8: Total Annual Burden Hours and Costs to Federal Government

Information Collection No.	# of Facilities	Hourly Wage	Hours/ Task	Total Burden Hours	Total Burden Costs
IC-1: 483.460(a)(4) - One time development of policies					
Existing Facilities	5,523	\$91	4	22,092	\$2,010,372
Newly Certified Facilities	24	\$91	4	96	\$8,736
IC-2: 483.460(a)(4) - Annual update of policies	5,523	\$91	1	5,523	\$502,593
IC-3: 483.460(a)(4)(ii), (iii), and (iv) - One time development of educational materials					
Existing Facilities	5,523	\$91	4	22,092	\$2,010,372
Newly Certified Facilities	24	\$91	4	96	\$8,736
IC-4: 483.460(a)(4)(ii), (iii), and (iv) - Annual update of educational materials	5,523	\$91	1	5,523	\$502,593
Costs to Perform Survey over 3 years				55,422	\$5,043,402

²³ The hourly median wage for BLS Occupation Code 13-1041 (Compliance Officer – Federal/State Government) for the Residential Intellectual and Developmental Disability Facilities Sector is \$45.35 per May 2023 OEWS Industry-Specific Occupational Employment and Wage Estimates (bls.gov) accessed at: https://www.bls.gov/oes/current/naics5_623210.htm. Applying 100% for benefits and rounded up, the loaded hourly median wage is \$91.

Information Collection No.	# of Facilities	Hourly Wage	Hours/ Task	Total Burden Hours	Total Burden Costs
Other Costs				30	\$1,710
Total Cost to Federal Government				55,452	\$5,045,112
Number of FTEs				29	

Other Costs

In addition, the cost to the federal government also includes the cost to develop and submit this PRA package for OMB compliance. To determine this cost, we estimate the time it takes to develop and or update this PRA package. We estimate it takes about 90 hours per three-year period or about 30 hours per year or 0.01 FTEs to develop or update this package. Typically, a GS-13, step 1 federal government employee, located in Baltimore-Arlington, Washington D.C, Locality Pay Area of completes this PRA packages. According to The U.S. Office of Personnel Management, in 2024 the cost for this labor is \$56.52 per hour. The additional cost to complete this PRA package is \$1,710 per year.

Total Cost to the Federal Government

Total cost to the federal government is **\$5,045,112** per year ($\$5,043,402 + \$1,710 = \$5,045,112$) expressed as **55,452** hours per year ($55,422+30=55,452$) or 29 FTEs ($55,452 \text{ hours} / 1,920 \text{ hours} = 29 \text{ FTEs}$).

15. Changes to Burden

The annual burden to industry decreased from 114,478 hours to 75,721 hours. The decrease in burden hours is primarily due to the elimination of the CoP at Section 483.430(f) requiring ICFs-IID to document the “educate and offer of the COVID-19 vaccine” task for every staff member. A small portion of the decrease is also due to an overcount of hours in the prior package for Year 1 in Information Collection No. 3, discussed in detail in footnote 12.

16. Publication/Tabulation Dates

There are no plans to publish the information.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

We have not identified any exceptions.