



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10330, CMS-10777 and CMS-10598]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

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

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain) . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA web site by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Rescission of Coverage and Disclosure Requirements for Patient Protection under the Affordable Care Act; *Use:* Section 2712 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act, contains a rescission notice. The No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, sunset the patient protections related to choice of health care professional under section 2719A of the PHS Act and recodified these patient protections in newly added section 9822 of the Internal Revenue Code, section 722 of the Employee Retirement Income Security Act, and section 2799A-7 of the PHS Act and extended the applicability of these provisions to grandfathered health plans for plan years beginning on or after January 1, 2022. The rescission notice will be

used by health plans and issuers to provide advance notice to certain individuals that their coverage may be rescinded as a result of fraud or intentional misrepresentation of material fact. The patient protection notification will be used by certain health plans and issuers to inform individuals of their right to choose a primary care provider or pediatrician and to use obstetrical/gynecological services without prior authorization. The related provisions are finalized in the 2015 final regulations titled “Final Rules under the Affordable Care Act for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections” (80 FR 72192, November 18, 2015) and 2021 interim final regulations titled “Requirements Related to Surprise Billing; Part I” (86 FR 36872, July 13, 2021). *Form Number*: CMS-10330 (OMB control number: 0938-1094); *Frequency*: Annual; *Affected Public*: State, Local, or Tribal Governments, Private Sector; *Number of Respondents*: 82,638; *Total Annual Responses*: 13,741,303; *Total Annual Hours*: 10. (For policy questions regarding this collection, contact Adam Pellillo at 667-290-9621.)

2. *Type of Information Collection Request*: Reinstatement with change of a previously approved collection; *Title of Information Collection*: Conditions of Participation for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID); *Use*: 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.

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. 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.

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. 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. 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. 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. Currently, ICFs-IID must continue to 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.

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. *Form Number*: CMS-10777 (OMB control number 0938-1402); *Frequency*: Annually; *Affected Public*: Private Sector – Business or other for-profits and not-for-profits institutions; *Number of Respondents*: 5,523; *Total Annual Responses*: 5,523; *Total Annual Hours*: 75,721. (For policy questions regarding this collection contact Claudia Molinar at 410-786-8445.)

3. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Evaluation of Stakeholder Training and Program Support; *Use*: The Centers for Medicare and Medicaid Services (CMS) provides training and technical assistance primarily through weekly, bi-weekly, monthly, or quarterly webinars, conferences, and Computer Based Trainings (CBTs). In addition, CMS provides one-time web-based training and support sessions as needed. Evaluation instruments are electronically sent to participants immediately after each session. Current data collections include online and onsite training session evaluations.

CMS uses information from the data collection activities to determine the extent to which the goals of each training and support session were achieved and to help CMS make improvements for future training and support sessions. The collected data helps CMS address its Government Performance and Results Act (GPRA) requirements, as well as CMS and HHS goals for support for, and open dialogue with, stakeholders.

The Affordable Care Act (ACA) was enacted to assist millions of Americans in obtaining affordable health care services and to allow more employers to offer insurance coverage to their employees in a cost-effective manner. Since the implementation of ACA in 2014, individuals and small businesses have been able to purchase private health insurance through competitive marketplaces called the “Health Insurance Marketplace” (Marketplace). CMS issued regulations for the establishment and practices of Marketplaces in States. The cooperation and coordination

of States, health insurance issuers, the Federal Government and other key stakeholders is essential to the continued success of the Marketplace.

The Consolidated Appropriations Act (CAA) of 2021 became law on December 27, 2020. It is a \$1.4 trillion omnibus spending agreement that encompasses many different provisions. Two (2) acts within the law apply to the Centers for Medicare and Medicaid Services (CMS) Center for Consumer Information and Insurance Oversight (CCIIO): Title I, “No Surprises Act” and Title II, “Transparency” (NST). Beginning in 2022, new protections through the No Surprises Act are in place to shield millions of consumers from surprise medical bills.

CMS is strongly committed to providing training, outreach, and technical assistance to stakeholders participating in the Marketplace and/or programs mandated by the ACA or NST. In addition, CMS recognizes that the success of Marketplaces and associated programs relies on the cooperation and coordination of States, issuers, Assisters, self-insured health plans, third-party administrators (TPA) of self-insured health plans, agents and brokers, Providers/Facilities, and other stakeholders. Therefore, CMS expects to design and conduct various consumer satisfaction and feedback surveys, usability tests, and focus groups for these respondents to complete. *Form Number:* CMS-10598 (OMB control number: 0938-1331); *Frequency:* Annually; *Affected Public:* Individuals and Households, Private Sector, State, Local, and Tribal Governments, Federal Government, Business or other for-profit, and not-for-profit institutions; *Number of Respondents:* 9,588; *Number of Responses:* 9,588 *Total Annual Hours:* 2,397 hours. (For policy questions regarding this collection contact Sonia Henderson at 301-492-4320.)

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**William N. Parham, III**

*Director,*

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