PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

	Inclusion criteria	Exclusion criteria
Setting	KQ 1—KQ 5. All clinical settings	NA
Study Design	KQs 1, 2. Randomized controlled trials	KQs 1, 2: Other designs.
	KQs 3–5. Randomized controlled trials. Comparative cohort studies with concurrent control groups, conducted within the same clinical setting. Other observational studies with concurrent control groups, that control for confounders.	KQs 3–5: Uncontrolled cohort studies, case-control studies, case reports, case series, cost-effectiveness and other modeling studies.
	Studies conducted in countries rated as very high on the Human Development Index.[a]	Studies using nonconcurrent comparators (*e.g.,* historical controls).
		Studies comparing methods across different settings/clinics.
		Observational studies that do not control for confounders.

Abbreviations: CF = conventionally fractionated external beam radiation therapy; CT = computed tomography; CRT = conventional radiotherapy; EBRT = external beam radiation therapy; ED = erectile dysfunction; GI = gastrointestinal issues; GU = genitourinary issues; Gy = gray; IMPT = intensity modulated proton therapy; KQ = key question; MHF = moderately hypofractionated radiation therapy; MRI = magnetic resonance imaging; MR-linac = MRI-guided linear accelerator; NA = not applicable; OARs = organs at risk; PET = positron emission tomography; PICOTS = population, interventions, comparators, outcomes, timing, and setting; SABR = stereotactic ablative radiotherapy; SBPT = stereotactic body proton therapy; SBRT = stereotactic body radiation therapy; UHF = ultra-hypofractionated radiation therapy; VMAT = volumetric modulated arc therapy.

[a] United Nations Development Programme. Human Development Index. Retrieved from *https://hdr.undp.org/data-center/human-development-index#/indicies/HDI.*

Dated: January 7, 2025.

Marquita Cullom,

Associate Director.

[FR Doc. 2025–00547 Filed 1–13–25; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10777, CMS–R–235 and CMS–10662]

Agency Information Collection Activities: Proposed Collection; 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by March 17, 2025.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 website 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 N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

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

CMS–R–235 Data Use Agreement (DUA) Limited Data Set (LDS) Forms Research Identifiable Files (FIF) Forms

CMS–10662 Administrative Simplification HIPAA Compliance Review

Under the 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 requires Federal agencies to publish a 60-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.

Information Collections

1. 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.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Use Agreement (DUA) Limited Data Set (LDS) Forms Research Identifiable Files (FIF) Forms; *Use:* The Privacy Act of 1974, § 552a requires the Centers for Medicare & Medicaid Services (CMS) to track all disclosures of the agency's Personally Identifiable Information (PII). CMS is also required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Federal Information Security Management Act (FISMA) of 2002 to properly protect all Protected Health Information (PHI) data maintained by the agency and account for the disclosure of PHI. When entities, such as academic, Federal or State agency

researchers or CMS contractors request CMS PII/PHI data, they enter into a Data Use Agreement (DUA) with CMS. The DUA stipulates that the recipient of CMS data must properly protect the data according to all applicable data security standards and provide for its appropriate destruction at the completion of the project/study or the expiration date of the DUA.

CMS is permitted to disclose data files for approved research purposes in compliance with 45 CFR 164.512(I). Researchers requesting limited data set files (LDS) must, as part of the request process, complete a research request packet that provides CMS with information pertaining to the research study, including describing how the research results/findings will be disseminated, as well as the data files being requested. Should CMS approve the research request, the data requestor enters into a Data Use Agreement (DUA). This data collection is necessary to ensure that disclosures of data for research purposes comply with Federal laws and regulations as well as CMS policy. *Form Number:* CMS–R–235 (OMB control number 0938–0734); *Frequency:* Occasionally; *Affected Public:* Private Sector—State, Local, or Tribal Governments; and Business or other for-profits, Not-for-profits institutions and Federal Government *Number of Respondents:* 7,805; *Total Annual Responses:* 7,805; *Total Annual Hours:* 4,234. (For policy questions regarding this collection contact Rebecca Dorman at 410–786–2095 or *rebecca.dorman@cms.hhs.gov*.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Administrative Simplification HIPAA Compliance Review; *Use:* The purpose of this collection is to retrieve information necessary to conduct a compliance review and carry out the authority delegated to CMS as described in CMS–0014–N (68 FR 60694). These forms will be submitted to the Centers for Medicare & Medicaid Services (CMS), National Standards Group, from entities covered by HIPAA Administrative Simplification regulations. This collection is not applicable to HIPAA Privacy and Security Rules. *Form Number:* CMS–10662 (OMB control number 0938–1390); *Frequency:* Annually; *Affected Public:* Private Sector—State, Local, or Tribal Governments; and Business or other for-profits, Not-for-profits institutions and Federal Government; *Number of Respondents:* 100; *Total Annual Responses:* 140; *Total Annual Hours:* 3,040. (For policy questions regarding this collection contact Kevin Stewart at 410–786–6149 or *Kevin.stewart@cms.hhs.gov*.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–00593 Filed 1–13–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10203]

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 February 13, 2025.

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.* 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 website 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:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Health Outcomes Survey; *Use:* The HOS is a longitudinal patient-reported outcome measure (PROM) that assesses self-reported beneficiary quality of life and daily functioning. As a PROM, the HOS measures the impact of services provided by MAOs, whereas process and patient experience measures only provide a snapshot of activities or experiences at a specific point in time. PROM data collected by the HOS allows CMS to continue to assess the health of the Medicare Advantage population. This older population is at increased risk of adverse health outcomes, including chronic diseases and mobility impairments that may significantly hamper quality of life. The HOS supports CMS's commitment to improve health outcomes for beneficiaries while reducing burden on providers. CMS accomplishes this by focusing on high-priority areas for quality measurement and improvement established in the agency's Meaningful Measures Framework. The HOS uses quality