TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background on Common Formats Development

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), 42 U.S.C. 299b-21 to b-26, and the related Patient Safety and Quality Improvement Final Rule (Patient Safety Rule), 42 CFR part 3, published in the **Federal Register** on November 21, 2008, 73 FR 70731–70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The collection of patient safety work product allows for the aggregation of data that help to identify and address underlying causal factors of patient safety and quality issues.

The Patient Safety Act provides for AHRQ to develop standardized reporting formats using common language and definitions (Common Formats) for reporting on health care quality and patient safety that will ensure that data collected by PSOs and other entities have comparable clinical meaning. The Common Formats facilitate aggregation of comparable data at local, PSO, regional and national levels. In addition, the Common Formats are intended to enhance the reporting of information that is standardized.

Since February 2005, AHRQ has convened the Federal Patient Safety Work Group (PSWG) to assist AHRQ in developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS as well as the Departments of Defense and Veterans Affairs. The PSWG helps assure the consistency of definitions/formats with those of relevant government agencies. In addition, AHRQ has solicited comments from the private and public sectors, since 2008, regarding proposed versions of the Common Formats through a contract with the National Quality Forum (NQF), which is a non-profit organization focused on health care quality. After receiving comments, the NQF solicits review of the formats by its Common Formats Expert Panel. Subsequently, NQF provides this input to AHRQ who then uses it to refine the Common Formats before issuing a production version.

AHRQ previously developed and maintains Common Formats for three settings of care—acute care hospitals, skilled nursing facilities, and community pharmacies—for use by healthcare providers and PSOs. AHRQ-listed PSOs are required to collect patient safety work product in a standardized manner to the extent practical and appropriate, a requirement the PSO can meet by collecting such information using Common Formats. Additionally, health care providers and other organizations not working with an AHRQ-listed PSO can use the Common Formats in their work to improve quality and safety; however, they cannot benefit from the federal confidentiality and privilege protections of the Patient Safety Act.

The CFER–DS is the first AHRQ Common Formats for Event Reporting that can be used across healthcare settings. It is designed to capture standardized, structured data to facilitate the reporting of diagnostic safety events for the purpose of learning about how to improve diagnostic safety and better support clinicians in the diagnostic process.

The CFER–DS is not designed for frontline incident reporting. It is intended to facilitate the collection and organization of a basic set of meaningful data about diagnostic safety events that can be used, aggregated and analyzed for learning and improvement. Having a common frame of reference and standardized data elements is what makes shared learning possible at local, regional and national levels. Users decide if and how to integrate collection of specific data elements into their incident reporting systems and other existing work processes.

AHRQ is specifically interested in receiving feedback in order to guide improvement of the CFER–DS V0.1. As with other Common Formats, the Event Description is available for public comment. Additionally, AHRQ is seeking feedback on a user guide and a form. Additional supporting documentation will be finalized and made available following AHRQ's receipt of comment from the public and NQF's Common Format Expert Panel. Information on how to comment is available at: *http://www.qualityforum.org/Project_Pages/Common_Formats_for_Patient_Safety_Data.aspx.*

Additional information about the AHRQ Common Formats can be obtained through AHRQ's PSO website: *https://pso.ahrq.gov/common-formats.*

Dated: May 25, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–11386 Filed 5–28–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–29, CMS–437 and 10452]

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 July 1, 2021.

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, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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:* Verification of Clinic Data—Rural Health Clinic Form and Supporting Regulations; *Use:* The form is utilized as an application to be completed by suppliers of Rural Health Clinic (RHC) services requesting participation in the Medicare program. This form initiates the process of obtaining a decision as to whether the conditions for certification are met as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Automated Survey Process Environment (ASPEN) and related survey and certification databases by the CMS Regional Offices. Should any question arise regarding the structure of the organization, this information is readily available. *Form Number:* CMS–29 (OMB control number 0938–0074); *Frequency:* Occasionally (initially and then every six years); *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 1,887; *Total Annual Responses:* 5,661; *Total Annual Hours:* 1,269. (For policy questions regarding this collection contact Shonte Carter at 410–786–3532.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Psychiatric Unit Criteria Work Sheet; *Use:* Certain specialty hospitals and hospital specialty distinct-part units may be excluded from the Inpatient Medicare Prospective Payment System (IPPS) and be paid at a different rate. These specialty hospitals and distinct-part units of hospitals include Inpatient Rehabilitation Facilities (IRFs) units, Inpatient Rehabilitation Facilities (IRFs) hospitals and Inpatient Psychiatric Facilities (IPFs).

CMS regulations at 42 CFR 412.20 through 412.29 describe the criteria under which these specialty hospitals and specialty distinct-part hospital units are excluded from the IPPS. Form CMS–437 is used by Inpatient Psychiatric Facilities (IPFs) to attest to meeting the necessary requirements that make them exempt for receiving payment from Medicare under the IPPS. These IPFs must use CMS–437 to attest that they meet the requirements for IPPS exempt status prior to being placed into excluded status. The IPFs must re-attest to meeting the exclusion criteria annually. *Form Number:* CMS–437 (OMB control number: 0938–0358); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 1,598; *Total Annual Responses:* 1,598; *Total Annual Hours:* 1,732. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

3. *Type of Information Collection Request:* Extension of a previously approved collection; *Title of Information Collection:* CMS Identity Management (IDM) System; *Use:* HIPAA regulations require covered entities to verify the identity of the person requesting Personal Health Information (PHI) and the person's authority to have access to that information. Per the HIPAA Security Rule, covered entities, regardless of their size, are required under Section 164.312(a)(2)(i) to ''assign a unique name and/or number for identifying and tracking user identity.'' A 'user' is defined in Section 164.304 as a ''person or entity with authorized access''. Accordingly, the Security Rule requires covered entities to assign a unique name and/or number to each employee or workforce member who uses a system that receives, maintains or transmits electronic PHI, so that system access and activity can be identified and tracked by user. This pertains to workforce members within health plans, group health plans, small or large provider offices, clearinghouses and beneficiaries.

The information collected will be gathered and used solely by CMS, approved contractor(s), and state health insurance exchanges to prove the identity of an individual requesting electronic access to CMS protected information or services. Information confidentiality will conform to the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Federal Information Security Management Act (FISMA) requirements. Respondents may also access CMS' Terms of Service and Privacy Statement on the CMS Portal and IDM websites.

CMS has moved from this centralized on premise model for enterprise identity management to a cloud-based solution, IDM, with multiple products providing specialized services: Okta Identity as a Service (IDaaS), which includes Multi-Factor Authentication (MFA) services; Experian Remote Identity Proofing (RIDP) services; and Cloud Computing Services-Amazon Web Services/ Information Technology Operations (CCS–AWS/ITOps) Hub Hosting. In order to prove the identity of an individual requesting electronic access to CMS protected information or services, IDM (leveraging Experian Precise ID RIDP services) will collect a core set of attributes about that individual. *Form Number:* CMS–10452 (OMB control number: 0938–1236); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 560,000; *Total Annual Responses:* 560,000; *Total Annual Hours:* 186,667. (For policy questions regarding this collection contact Malachi Robinson at 410–786–1849).

Dated: May 26, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–11491 Filed 5–28–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–179 and CMS–10775]

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 (the PRA), federal agencies are required to publish notice in the **Federal Register**