4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10798, CMS-R-235, CMS-359/CMS-360, and CMS-10069]

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. 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:* Reinstatement with change to a previously approved information collection; *Title*: Application for Part B Immunosuppressive Drug Coverage (Part B-ID); *Use*: Sections 226A, 1836(b) and 1837(n) of the Act provide the statutory authority for this new, limited Medicare entitlement program. It is stated in § 407.1(a)(6) that, sections 1836(b) and 1837(n) of the Act provide for coverage of immunosuppressive drugs as described in section 1861(s)(2)(J) of the Act under Part B beginning on or after January 1, 2023, for eligible individuals whose benefits under Medicare Part A and eligibility to enroll in Part B on the basis of ESRD would otherwise end with the 36th month after the month in which the individual receives a kidney transplant by reason of section 226A(b)(2) of the Act.

CMS-10798 provides the necessary information to determine eligibility and to process the beneficiary's request for enrollment for in Part B-ID coverage. This form is only used for enrollment by beneficiaries whose Medicare entitlement based on ESRD would otherwise end after a successful kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs who already have Part A, but not Part B.

Form CMS-10798 is completed by the individual or is completed by an SSA representative using information provided by the Medicare enrollee during a telephone interview. The form is owned by CMS but not completed by CMS staff. SSA processes Medicare enrollments on behalf of CMS. *Form Number*: CMS-10798 (OMB control number: 0938-1428); *Frequency*: Once; *Affected Public:* Individuals and Households, State, Local, or Tribal Governments; *Number of Respondents*: 1,019; *Total Annual Responses*: 1,019; *Total Annual Hours*: 173. (For policy questions regarding this collection contact Tyrissa Woods at 410-786-0286 or Tyrissa.woods@cms.hhs.gov .)

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, section 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:* Reinstatement with change of a previously approved information collection; *Title of Information Collection:* Comprehensive Outpatient Rehabilitation Facility (CORF) Certification and Survey Forms; *Use:* This information collection is for the reinstatement of the CMS-359 and CMS-360 forms. The purpose of these forms is described below. The form CMS-359 is an application for health care providers that seek to participate in the Medicare program as a Comprehensive Outpatient Rehabilitation Facility (CORF). The form initiates the process for facilities to become certified as a CORF and it provides the CMS Location and State Survey Agency (SA) staff identifying information regarding the applicant that is stored in the Automated Survey Processing Environment (ASPEN) system.

The form CMS-360 is a survey tool used by the SAs to record information in order to determine a provider's compliance with the CORF Conditions of Participation (COPs) and to report this information to the Federal Government. The form includes basic information on the

COP requirements, check boxes to indicate the level of compliance, and a section for recording notes. CMS has the responsibility and authority for certification decisions which are based on provider compliance with the COPs and this form supports this process. *Form Number:* CMS-359/360 (OMB control number: 0938-0267); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 179; *Number of Responses:* 31; *Total Annual Hours*: 241. (For questions regarding this collection contact Caroline Gallaher (410)786-8705.)

4. *Type of Information Collection Request*: Reinstatement with change of a previously approved collection; *Title of Information Collection:* Rural Community Hospital Demonstration Program Application; *Use*: CMS is requesting the information collection request previously approved under OMB control number 0938-0880, the Medicare Waiver Demonstration/Model Application, be reinstated. The approval lapsed due to an administrative oversight.

The Centers for Medicare & Medicaid Services (CMS) has operated the statutory Rural Community Hospital (RCH) Demonstration since 2004. The authorizing statute instructed CMS to test cost-based payment for Medicare inpatient services for rural hospitals with fewer than 51 beds that are not eligible to be Critical Access Hospitals (CAH).

The RCH Demonstration Program was initially authorized by section 410A of the Medicare Modernization Act (MMA) of 2003. Following the initial 5-year authorization, the demonstration has been extended 3 times, each time for an additional 5 years – first, by Sections 3123 and 10313 of the Affordable Care Act; then by section 15003 of the 21st Century Cures Act; and by section 128 of the Consolidated Appropriations Act of 2021. Currently, the demonstration has 20 participants out of a maximum of 30 hospitals, and it is scheduled to end in 2028.

For previous authorizations, CMS has issued a Request for Applications (RFA) to solicit applications for the demonstration program. For the last solicitation, in 2017, CMS received 51

applications for 13 open spaces. CMS is planning on a new RFA to fill the ten spaces that are currently open.

Per the RFA, applications are requested in identical format, regardless of the specific goals and projects of the individual applicants. The standardized application format is not controversial, and it will reduce burden on applicants and reviewers. Responses are strictly voluntary. The standard format will enable CMS to select proposals that meet CMS objectives and show the best potential for success.

The RFA will ask interested hospitals to provide a problem statement, strategies for ongoing financial viability, goals for participation in the demonstration, and plans for collaboration with other providers in the area. Applications will be submitted in the user-friendly format outlined in the Medicare Waiver Demonstration/Model Application.

A panel of evaluators will be assembled and utilize a standardized rubric to score the submitted proposals and identify hospitals with the highest scores. Results will be used to guide the future of the Medicare and Medicaid programs and to inform reform initiatives. *Form Number*: CMS-10069 (OMB control number: 0938-0880); *Frequency*: Once; *Affected Public*: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 2,400. (For policy questions regarding this collection contact Alexis Lilly at 410-786-3501).

William N. Parham, III

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

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