DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10913]

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 January 22, 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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request; *Use:* Section 1857(d) of the Act, added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR 422.503 and 422.504 state that CMS must oversee an MA organization's continued compliance with the requirements for a MA organization. Additionally, per § 422.516(a), MA organizations are required to compile and report to CMS information related to the utilization of services, and other matters as CMS may require.

The information gathered during this annual data collection and audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) to assess Sponsoring organizations' compliance with Medicare UM requirements. CMS will utilize the data submitted during the annual data submission to assess the number of items and services that have associated internal coverage criteria, and to develop a landscape of items and services across the nation to assess trends related to the development and utilization of internal coverage criteria. Additionally, CMS will use the annual submission to select a number of Sponsoring organizations to undergo UM audits each year, and to select specific items and services to audit. Annual UM data submissions, for all Sponsoring organizations, will be due to CMS by January 31 of each calendar year. *Form Number:* CMS–10913 (OMB control number: 0938–new); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 179; *Total Annual Responses:* 179; *Total Annual Hours:* 19,180. (For policy questions regarding this collection contact Caroline Zeman at 410–786–1564).

William N. Parham, III,

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

[FR Doc. 2024–30619 Filed 12–20–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–52]

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 February 21, 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–R–52 End Stage Renal Disease (ESRD) Conditions for Coverage and Supporting Regulations

CMS–10901 Expanding Access to Women's Health Grant

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:* End Stage Renal Disease (ESRD) Conditions for Coverage and Supporting Regulations; *Use:* The Centers for Medicare and Medicaid Services (CMS) is requesting reinstatement of OMB Control number 0938–0386 (CMS–R–52) in compliance with the Paperwork Reduction Act (PRA). This package applies to existing Medicare End-stage Renal Disease (ESRD) conditions for coverage (CfCs) at 42 CFR 494. Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603) originally extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292) amended title XVIII of the Social Security Act (the Act) by adding section 1881. Section 1881(b)(1) of the Act authorizes the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services to patients must meet to qualify for Medicare reimbursement. Final regulations were published June 3, 1976. Subsequent to the publication of the final regulations, the ESRD Amendments of 1978 were enacted to amend title XVIII of the Act to include section 1881(c). This section establishes ESRD network areas and Network organizations to assure the effective and efficient administration of ESRD program benefits. The requirements from section 1881(b) and (c) are implemented in regulations at 42 CFR part 405, subpart U, Conditions for Coverage for dialysis facilities.

On April 7, 1986, the Consolidated Omnibus Budget Reconciliation Act of 1975 (COBRA) (Pub. L. 99–272) was enacted which requires the Secretary to maintain renal disease Network organizations as authorized under section 1881(c) of the Act, and not merge the Network organizations into other organizations or entities. On April 15, 1986, we published a notice of proposed rulemaking to implement section 9214 of Public Law 99–272. A final rule (HSQ–115) was published August 26, 1986 which included information collection requirements at § 405.2112(e). This rule revised the requirements in regulations pertaining to the ESRD networks and organizations and establishes new, more efficient Network organizations.

Revisions resulting from two additional rules: HSQ–137—ESRD: Responsibilities of Network Organizations, published January 21, 1988; and BERC–434—Medicare Program: Standards for the Reuse of Hemodialyzer Filters and Other Dialysis Supplies, published October 2, 1987, are also included. HSQ–137–ESRD approved information collection requirements at §§ 405.2112(f) and (j). BERC–434 approved information collection requirements stemming from the following historical sections of the CFR including §§ 405.2136(b), 405.2138(a), 405.2139(a), and 405.2140(b) and (c).

Major revisions to the CFR established new ESRD CfCs at 42 CFR 494 issued in a final rule, ''*Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities,*'' published on April 15, 2008 (CMS–3818–F). This rule modified, removed, added, and redesigned CfCs that dialysis facilities must meet to be certified under the Medicare program. This rule approved information collection requirements at §§ 494.30, 494.40, 494.50, 494.60, 494.70, 494.80, 494.90, 494.100, 494.110, 494.120, 494.150, 494.170, and 494.180.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by CMS–3818–F at 414.330(a)(2)(iii)(C). The burden to ESRD home dialysis suppliers associated with this requirement would be the time and effort necessary to collect all data for each patient receiving home dialysis care with respect to services and items furnished. However, the payment method that covered these suppliers was eliminated in 2011 and there are no longer any such entities. See 42 CFR parts 410, 413 and 414 Medicare Program; End-Stage Renal Disease Prospective Payment System; Final Rule and Proposed Rule at the following link **Federal Register** *https://www.govinfo.gov/content/pkg/FR-2010-08-12/pdf/2010-18466.pdf.*

Therefore, there are no actual costs associated with this requirement; we removed it from this package.

An additional revision to the ESRD CfCs at 42 CFR part 494 was precipitated by interim final rule, ''*Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment,*'' published on December 14, 2016 (CMS–3337–IFC). This rule established new requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans. This interim final rule

established additional burden associated with §§ 494.70(c) and 494.180(k); these were quantified in the preceding information collection which expired in 2024 (OMB Control Number 0938–0386). Since these regulations were not finalized due to litigation, they are no longer in effect. Therefore, we took out these sections from this package as they do not impose any burden.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by final rule, ''*Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers,*'' published September 16, 2016 (CMS–3178–F). This rule established the creation and maintenance of an Emergency Preparedness Plan at 494.62(a), an Emergency Preparedness Policies and Procedures document at 494.62(b), an Emergency Preparedness Communication Plan at 494.62(c), a training program 494.62(d), and documentation of training exercises 494.62(e). These information collections are in separate package, OMB Control number 0938–1325.

On July 5, 2024, revisions to the CfC were proposed in ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'', (CMS–1805–P). This rule proposed to expand coverage of home dialysis services to patients with acute kidney injury (AKI). Since the ESRD CfCs apply to dialysis facilities, not to people with ESRD, this rule proposes to revise language in the CfCs to allow beneficiaries with AKI to utilize home dialysis. Specifically, we refer to facilities abiding by the ESRD CfCs as 'dialysis facilities' opposed to 'ESRD facilities and all patients seeking services from dialysis facilities as 'patients' rather than 'ESRD patients.' There is no ICR burden associated with these changes however we made confirming changes to the language in this package.

The CfCs are used by Federal (CMS), State surveyors (employed by State survey agencies), or CMS authorized accrediting organizations as a basis for determining whether a dialysis facility qualifies for approval or re-approval under Medicare. Surveyors make an in-person visit to the dialysis facility to perform the complete survey.

The preceding information collection, which expired on March 31, 2024, estimated the total annual hourly burden as 1,260,491 hours at a cost of $64,839,657. We revise this to 800,621 hours at a cost of $49,638,502. The reduction in hours and cost is largely due to removing the burden estimates that no longer apply. *Form Number:* CMS–R–52 (OMB Control Number: 0938–0386); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 8,048; *Total Annual Responses:* 215,591; *Total Annual Hours:* 800,621 (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of information Collection:* Expanding Access to Women's Health Grant; *Use:* On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 was also signed into law (collectively referred to as the ''ACA''). The ACA includes a number of provisions that reform the health insurance markets and provide Federal consumer protections through amendments to title XXVII of the Public Health Service Act (PHS Act) and corresponding amendments to the Employee Retirement Income Security Act and the Internal Revenue Code. The ACA also includes significant grant funding for States to work with the Federal Government to implement the Federal market reforms and consumer protections.

Section 1003 of the ACA adds a new section 2794 to the PHS Act entitled, ''Ensuring That Consumers Get Value for Their Dollars.'' Specifically, section 2794(a) requires the Secretary of the Department of Health and Human Services (the Secretary) (HHS), in conjunction with the States, to establish a process for the annual review of health insurance premiums to protect consumers from unreasonable rate increases. Section 2794(c) directs the Secretary to carry out a program to award grants to States. The data collection (quarterly and final reports) are a source of information on the State's progress with meeting CMS expectations for the Expanding Access to Women's Health Grant. The reports describe significant advancements towards the State's goal of enhancing and expanding access to reproductive and maternal health coverage and services from the beginning of the grant period through the completion of the grant period. The data collection is imperative to CMS being able to assess the State's progress, barriers, and updates on measurable objectives. Without the data collection, CMS will be unable to efficiently monitor the State's progress. It will also inhibit CMS' ability to support and share opportunities of best practices with other States. *Form Number:* CMS–10901 (OMB control number 0938–NEW); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 15; *Total Annual Responses:* 68; *Total Annual Hours:* 840. (For policy questions regarding this collection contact Jim Taing at *James.Taing@cms.hhs.gov.*)

William N. Parham, III,

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

[FR Doc. 2024–30502 Filed 12–20–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Drug Evaluation and Research (CDER), Office of Medical Policy (OMP) has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on November 19, 2024.

FOR FURTHER INFORMATION CONTACT: Jennifer Wade, Acting Director, Division of Reorganizations and Delegations of Authority, Office of Budget, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–731–0192.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the FDA's reorganization of the CDER, OMP.