DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–2728]

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 13, 2023.

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–2728 End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration

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 Collection

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Use:* Section 226A (2) of the Social Security Act specifically states that a person must be ''medically determined to have end stage renal disease . . . .'' Similarly, Section 188(a) of the law states ''The benefits provided by parts A and B of this title shall include benefits for individuals who have been determined to have end stage renal disease as provided in Section 226A''. The End Stage Renal Disease (ESRD) Medical Evidence (CMS–2728) is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life.

The data reported on the CMS–2728 is used by the Federal Government, ESRD Networks, treatment facilities, researchers and others to monitor and assess the quality and type of care provided to end stage renal disease beneficiaries. The data collection captures the specific medical information required to determine the Medicare medical eligibility of End Stage Renal Disease claimants. It also collects data for research and policy on this population.

The three main data systems available for evaluating the ESRD program and for monitoring epidemiology, access, and quality and reimbursement effects on quality are: (1) The United States Renal Data System (USRDS) provides basic data on patterns of incidence of ESRD in the United States. The USRDS database is intended to be used for biomedical research by investigators throughout the United States and abroad. The USRDS data is intended to supplement (and not replace) public use files produced by CMS. (2) United Network for Organ Sharing (UNOS) focus is on organ donation, transplantation and educational activities. (3) The ESRD Program Management and Medical System (PMMIS), maintained by CMS, provide the foundation data for the USRDS. This system, as required by Public Law 95–292, section C(1) (A), is designed to serve the needs of the Department of Health and Human Services in support of program analysis, policy development, and epidemiological research.

The ESRD PMMIS includes information on both Medicare and non-Medicare ESRD patients and on Medicare approved ESRD hospitals and dialysis facilities. The methods of ESRD data collection (*e.g.,* use of same forms, sharing of analysis) by CMS, UNOS, and USRDS have all agreed on a common data collection process that will provide needed additional information on the ESRD population.

Due to response by the provider community the CMS–2728 form has been revised by adding questions, clarifying questions, updating reasons for kidney failure, updating comorbidities to be more reflective of pediatric patients, and providing additional guidance and clarity in the instructions. *Form Number:* CMS–2728

(OMB control number: 0938–0046); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 7,828; *Total Annual Responses:* 138,000; *Total Annual Hours:* 138,000. (For policy questions regarding this collection contact Lisa Rees at (816) 426–6353).

Dated: December 12, 2022.

William N. Parham, III

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

[FR Doc. 2022–27233 Filed 12–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10527, CMS–10260, CMS–10836 and CMS–855A]

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 13, 2023.

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–10527 Annual Eligibility Redetermination, Product Discontinuation and Renewal Notice

CMS–10260 Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3)

CMS–10836 Medicare Plan Performance Warning Information

CMS–855A Medicare Enrollment Application for Institutional Providers

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 Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Eligibility Redetermination, Product Discontinuation and Renewal Notice; *Use:* Section 1411(f)(1)(B) of the Affordable Care Act directs the Secretary of Health and Human Services (the Secretary) to establish procedures to redetermine the eligibility of individuals for premium tax credits on a periodic basis in appropriate circumstances. Section 1321(a) of the Affordable Care Act provides authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, qualified health plans (QHPs) and other components of title I of the Affordable Care Act. Under section 2703 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act, and former section 2712 and section 2741 of the PHS Act, enacted by the Health Insurance Portability and Accountability Act of 1996, health insurance issuers in the group and individual markets must guarantee the renewability of coverage unless an exception applies.

The 2014 final rule ''Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges'' (79 FR 52994, September 5, 2014), provides that an Exchange may choose to conduct the annual redetermination process for a plan year (1) in accordance with the existing procedures described in 45 CFR 155.335; (2) in accordance with procedures described in guidance issued by the Secretary for the applicable benefit year; or (3) using an alternative procedure proposed by the Exchange and approved by the Secretary. The 2014 final rule established a renewal and reenrollment hierarchy at 45 CFR 155.335(j) to minimize potential enrollment disruptions. The 2016 final rule ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017'' (81 FR 12204, March 8, 2016) amended the enrollment