This document is scheduled to be published in the Federal Register on 2026-08-21 and available online at https://www.federalregister.gov/d/2026-17128, and on https://govinfo.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-2728 and CMS-10110]

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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 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 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**).

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:* Revision of a currently 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.

In October 2024, SDOH questions were formally activated within EQRS as part of the form. Concurrently, and in coordination with the Quality Incentive Program (QIP), questions 19, 21, 23, 24, and 25 were made unavailable for batch submission by dialysis organizations to reduce duplication with the QIP SDOH Screening Tool. Due to feedback from the stakeholder community the CMS-2728 form has been revised to remove SDOH vulnerability questions. Stakeholders unanimously agreed that SDOH questions are misplaced on the CMS-2728 since the form is a one-time admission document and is not designated to capture the dynamic, ongoing nature of social needs. Clinics already conduct SDOH assessments through established social worker workflows, and including questions on the CMS-2728 adds operational burden. *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:* 7,478; *Total Annual Responses*: 123,460; *Total Annual Hours:* 123,460. (For policy questions regarding this collection contact Christina Goatee at (410) 786-6689).

2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR

414.800-806; *Use*: Section 1847A of the Social Security Act (the Act) requires that the Medicare Part B payment amounts for covered drugs and biologicals not paid on a cost or prospective payment basis be based upon manufacturers' average sales price (ASP) data submitted quarterly to CMS. The reporting requirements are specified in 42 CFR part 414, subpart J. Section 1193(a)(5) of the Act requires a manufacturer that chooses to participate in the Medicare Drug Price Negotiation Program to comply with requirements determined by the Secretary to be necessary for purposes of administering the Medicare Drug Price Negotiation Program and monitoring compliance with the Medicare Drug Price Negotiation Program. Use of ASP reporting for a selected drug is part of CMS' Medicare Drug Price Negotiation Program administration and oversight of manufacturer compliance, under sections 1193(a)(5) and 1196(a)(1)-(3), (b) of the Act. This July 2026 iteration proposes to revise CMS' use of ASP data to support manufacturer effectuation of the maximum fair price for selected drugs payable under Part B for the purposes of the Medicare Drug Price Negotiation Program. *Form Number*: CMS-10110 (OMB control number: 0938-0921); *Frequency:* Quarterly; *Affected Public:* Private Sector; *Number of Respondents:* 500; *Total Annual Responses:* 4,500; *Total Annual Hours:* 49,500. (For policy questions regarding this collection contact: Elisabeth Daniel at 667-290-8793.)

William N. Parham, III

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026-17128 Filed: 8/20/2026 8:45 am; Publication Date: 8/21/2026]