

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-153]

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 October 20, 2026.

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**).

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:** Medicaid Drug Use Review (DUR) Program; **Use:** States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, e.g., allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy. The State must conduct retrospective drug use review which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact. The states and managed care organizations (MCOs) are provided the reporting instrument (a survey) by CMS, and by responding to the survey, the states generate annual reports which are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of states' DUR programs. The survey and the annual recordkeeping and reporting requirements under the pertinent regulations, are completed by pharmacists employed by, or contracted with the various state Medicaid programs and their MCOs. The annual reports submitted by states are reviewed and results are compiled by CMS in a format intended to provide information, comparisons and trends related to states' experiences with DUR. The states benefit from the information and may enhance their programs each year based on state reported innovative practices that are compiled by CMS from the annual reports. A comparison/summary of the data from the annual reports is published on *Medicaid.gov* annually, and serves as a resource for stakeholders, including but not limited

to states, manufacturers, researchers, congress, CMS, the Office of Inspector General, non-governmental payers and clinicians on the topic of DUR in state Medicaid programs. **Form Number:** CMS-R-153 (OMB control number: 0938-0659); **Frequency:** Yearly, quarterly, and occasionally; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 52; **Total Annual Responses:** 676; **Total Annual Hours:** 41,548. (For policy questions regarding this collection contact Mike Forman at 410-786-2666.)

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0008]

Advisory Committee; Oncologic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Oncologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Oncologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the September 1, 2028, expiration date.

DATES: Authority for the Oncologic Drugs Advisory Committee will expire on September 1, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993-0002, (301) 796-8220, ACOMSSubmissions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65, 21 CFR 14.40, and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the

Oncologic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least thirteen voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and other related professions.

Members may be invited to serve for terms of up to four years, or for less time in the discretion of the Commissioner or designee. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios.

In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative member(s), via a process consistent with legal and regulatory requirements. Individuals currently employed at FDA-regulated companies, such as pharmaceutical and medical device manufacturers, shall not be selected to serve as members of the Committee unless this Committee is expected to address issues for which inclusion of an industry representative is required by statute. If this Committee includes an industry representative, the Commissioner or designee will determine whether to invite them to participate in meetings on a case-by-case basis, according to applicable legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees to serve temporarily as