



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10156, CMS-10170, CMS-10110 and CMS-10488]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 THE 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, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

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 without change of a

currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy (RDS) Application and Instructions; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR part 423 subpart R plan sponsors (e.g., employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% subsidy for allowable drug costs. In order to qualify, plan sponsors must submit a complete application to the Centers for Medicare & Medicaid Services (CMS) with a list of retirees for whom it intends to collect the subsidy. Once CMS reviews and analyzes the information on the application and the retiree list, notification will be sent to the plan sponsor about its eligibility to participate in the Retiree Drug Subsidy (RDS) Program.

CMS has contracted with an outside vendor to assist in the administration of the RDS program; this effort is called the RDS Center. Plan Sponsors will apply on-line for the retiree drug subsidy by logging on to the RDS Secure Web Site. 42 CFR §423.844 describes the requirement for qualified retiree prescription drug plans who want to receive the retiree drug subsidy. Once the Plan Sponsor submits the RDS application via the RDS Secure Web Site (and a valid initial retiree list) CMS, through the use of its contractor, will analyze the application to determine whether the Plan Sponsor qualifies for the RDS. To qualify for the subsidy, the Plan Sponsor must show that its coverage is as generous as, or more generous than, the defined standard coverage under the Medicare Part D prescription drug benefit. *Form Number:* CMS-10156 (OMB control number: 0938-0957); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 1,803; *Total Annual Responses:* 1,803; *Total Annual Hours:* 115,392. (For policy questions regarding this collection contact Ivan Iveljic at 410-786-3312.)

2. *Type of Information Collection Request:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy Payment Request and Instructions; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR part 423 subpart R plan sponsors (e.g., employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% subsidy for allowable drug costs. In order to qualify, plan sponsors must submit a complete application to the Centers for Medicare & Medicaid Services (CMS) with a list of retirees for whom it intends to collect the subsidy. Once CMS reviews and analyzes the information on the application and the retiree list, notification will be sent to the plan sponsor about its eligibility to participate in the Retiree Drug Subsidy (RDS) Program. *Form Number:* CMS-10170 (OMB control number: 0938-0977); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,803; *Total Annual Responses:* 1,803; *Total Annual Hours:* 115,392. (For policy questions regarding this collection contact Ivan Iveljic at 410) 786-3312.)

3. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals; *Use:* Section 1847A of 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 data submitted quarterly to the Centers for Medicare & Medicaid Services (CMS). The reporting requirements are specified in 42 CFR Part 414 Subpart J.

The Division of Ambulatory Services (DAS), will utilize the ASP data (ASP and number of units sold as specific in section 1847A of the Act) to determine the Medicare Part B drug

payment amounts for CY 2005 and beyond. The manufacturers submit their ASP data for all of their NDCs for Part B drugs. DAS compiles the data, analyzes the data and runs the data through software to calculate the volume-weighted ASP for all of the NDCs that are grouped within a given HCPCS code. The formula to calculate the volume-weighted ASP is the Sum (ASP * units) for all NDCs/Sum (units * bill units per pkg) for all NDCs. DAS provides ASP payment amounts for several components within CMS that utilize 1847(A) payment methodologies to implement various payment policies including, but not limited to, ESRD, OPSS, OTP and payment models. The Department of Health and Human Services' Office of the Inspector General also uses the ASP data in conducting statutorily mandated studies. *Form Number:* CMS-10110 (OMB control number: 0938-0921); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 300; *Total Annual Responses:* 1,200; *Total Annual Hours:* 15,600. (For policy questions regarding this collection contact Felicia Eggleston at 410 786-9287.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Consumer Experience Survey Data Collection; *Use:* Section 1311(c)(4) of the Affordable Care Act requires the Department of Health and Human Services (HHS) to develop an enrollee satisfaction survey system that assesses consumer experience with qualified health plans (QHPs) offered through an Exchange. It also requires public display of enrollee satisfaction information by the Exchange to allow individuals to easily compare enrollee satisfaction levels between comparable plans. HHS established the QHP Enrollee Experience Survey (QHP Enrollee Survey) to assess consumer experience with the QHPs offered through the Marketplaces. The survey includes topics to assess consumer experience with the health care system such as communication skills of providers and ease of

access to health care services. CMS developed the survey using the Consumer Assessment of Health Providers and Systems (CAHPS®) principles (<https://www.ahrq.gov/cahps/about-cahps/principles/index.html>) and established an application and approval process for survey vendors who want to participate in collecting QHP enrollee experience data.

The QHP Enrollee Survey, which is based on the CAHPS® Health Plan Survey, will be used to (1) help consumers choose among competing health plans, (2) provide actionable information that the QHPs can use to improve performance, (3) provide information that regulatory and accreditation organizations can use to regulate and accredit plans, and (4) provide a longitudinal database for consumer research. Based on the requirements for the QHP Enrollee Survey, CMS developed this survey to capture information about enrollees' experience with QHPs offered through an Exchange. CMS conducted in-depth formative research including: a comprehensive literature review, review of existing CMS survey instruments, consumer focus groups, stakeholder discussions, and input from a Technical Expert Panel (TEP). CMS performed a psychometric test and beta test in 2014 and 2015, respectively. CMS began fielding the QHP Enrollee Survey nationwide in 2016 and this request is to continue nationwide collection and administration of the statutorily-required survey in 2021 through 2023. These activities are necessary to ensure that CMS fulfills legislative mandates established by section 1311(c)(4) of the Affordable Care Act to develop an "enrollee satisfaction survey system" and provide such information on Exchange websites. *Form Number:* CMS-10488 (0938-1221); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 285; *Total Annual Responses:* 82,510; *Total Annual Hours:* 16,517. For policy questions regarding this collection contact Nidhi Singh Shah at 301-492-5110.

Dated: August 5, 2020.

William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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