

Statistics or the American Statistical Association Conference etc.); hosting a statistical or health sciences fair or other STEM related competitions; organizing a STEM Career Day or similar activity; developing web-based sites or materials with youth focus as well as other programs developed to meet future

youth outreach needs, particularly activities that encourage STEM. Information will be collected using a combination of methodologies appropriate to each program. These may include: Registration forms, letters of recommendation, evaluation forms; mail surveys; focus groups; automated and electronic technology (e.g. email, Web-

based surveys); and telephone surveys. OMB approval is requested for three years to conduct the Youth Outreach Generic Clearance for the National Center for Health Statistics (NCHS). Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 1,750.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of survey	Respondent	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
Questionnaires/Applications	Student/Youth	800	1	30/60
Applicants Questionnaire/Application	Parents/Guardians of Applicants	800	1	30/60
Applications, Recommendations, and Other applicant-supporting documentation.	School Officials/Community Representatives	1200	1	30/60
Focus Groups	Student/Youth; Parent/Guardian; School Officials; Other.	50	1	60/60
Other Program Surveys	Student/Youth; Parent/Guardian; School Officials; Other.	600	1	30/60

**Jeffrey M. Zirger,**

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS-10110, CMS-10156, CMS-10728, and CMS-R-21]

**Agency Information Collection Activities: Proposed Collection; 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 (the 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 July 28, 2020.

**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, you may make your request using one of following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

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

**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-10110 Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals
- CMS-10156 Retiree Drug Subsidy (RDS) Application and Instructions
- CMS-10728 Value in Opioid Use Disorder Treatment Demonstration
- CMS-R-21 Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31

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 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, OPPS, 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.)

2. *Type of Information Collection Request:* Extension 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 website. 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 website (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.)

3. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Value in Opioid Use Disorder Treatment Demonstration; *Use:* Value in Opioid Use Disorder Treatment (Value in Treatment) is a 4-year demonstration program authorized under section 1866F of the Social Security Act (Act), which was added by section 6042 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The purpose of Value in Treatment, as stated in the statute, is to "increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical

and mental health outcomes for such beneficiaries, and to the extent possible, reduce Medicare program expenditures." As required by statute, Value in Treatment will be implemented no later than January 1, 2021.

Section 1866F(c)(1)(A)(ii) specifies that individuals and entities must apply for and be selected to participate in the Value in Treatment demonstration pursuant to an application and selection process established by the Secretary.

Section 1866F(c)(2)(B)(iii) specifies that in order to receive CMF and performance-based incentive payments under the Value in Treatment program, each participant shall report data necessary to: monitor and evaluate the Value in Treatment program; determine if criteria are met; and determine the performance-based incentive payment. *Form Number:* CMS-10728 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 12,096; *Total Annual Responses:* 12,096; *Total Annual Hours:* 1,285. (For policy questions regarding this collection contact Rebecca VanAmburg at 410-786-0524.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31; *Use:* Certain Medicaid providers that are subject to offsets for the collection of Medicaid overpayments may terminate or substantially reduce their participation in Medicaid, leaving the state Medicaid agency unable to recover the amounts due. Recovery procedures allow for determining the amount of overpayments and offsetting the overpayments by withholding the provider's Medicare payments. To effectuate the withholding, the state agency must provide their respective CMS regional office with certain documentation that identifies the provider and the Medicaid overpayment amount. The agency must also demonstrate that the provider was notified of the overpayment and that demand for the overpayment was made. An opportunity to appeal the overpayment determination must be afforded to the provider by the Medicaid state agency. Lastly, Medicaid state agencies must notify CMS when to terminate the withholding; *Form Number:* CMS-R-21 (OMB control number: 0938-0287); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual*

Responses: 27; Total Annual Hours: 81. (For policy questions regarding this collection contact Stuart Goldstein at 410-786-0694.)

Dated: May 21, 2020.

**William N. Parham, III,**

Director, Paperwork Reduction Staff, 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-10185]

#### 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 *June 29, 2020*.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

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](http://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 the following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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:* Revision with change of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements; *Use:* Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections, data are reported electronically to CMS. Each reporting section is

reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data should be entered at the Plan Benefit Package (PBP level, e.g., Plan 001 for contract H#, R#, S#, or E). Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C & D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution.

In accordance with Title I, Part 423, Subpart K (§ 423.514), the Act requires each Part D Sponsor to have an effective procedure to provide statistics indicating:

- The cost of its operations
- the patterns of utilization of its services
- the availability, accessibility, and acceptability of its services
- information demonstrating it has a fiscally sound operation
- other matters as required by CMS

Subsection 423.505 of the MMA regulation establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. *Form Number:* CMS-10185 (OMB control number: 0938-0992); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 744; *Total Annual Responses:* 17,080; *Total Annual Hours:* 25,256. (For policy questions regarding this collection contact Chanelle Jones at 410-786-8008.)

Dated: May 22, 2020.

**William N. Parham, III,**

Director, Paperwork Reduction Staff, 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-10537]

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

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.