ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mother, ASD workflow *Completed this study step*.	Clinic/Home Visit—Developmental Assessment(Attachment 7b, c, g), saliva collection (Attachment 8a–d), overall consent (Attachment 15a).	328	1	225/60
Father, ASD workflow *Completed this study step*.	Clinic/Home Visit—Saliva Collection (Attachments 8b–d).	164	1	15/60
Child, ASD workflow *Completed this study step*.	Clinic/Home Visit—Developmental Assessment (attachment 7a, 7d or 7e or 7f) and saliva collection (8a–d).	328	1	135/60
Mother, POP workflow *All potential participants sent mailing*.	Invitation Packet/Response Card (Attachments 10c, 10f, and 10g).	1,466	1	10/60
Mother , POP workflow *Potentially eligible with contact by study staff*.	Invitation Call Script (Attachment 11c) and Social Communication Questionnaire (Attachment 3).	733	1	30/60
Mother , POP workflow *Eligible, consented, and enrolled; assigned to the POP workflow based on enrollment intake*.	Enrollment Packet (Attachments 12a, c, d) ...	334	1	20/60
Mother, POP workflow *Completed this study step*.	Follow-up Phone Call Script and Checklist (Attachment 13) and Pregnancy Reference Form Attachments 5a and 5b).	301	1	15/60
Mother, POP workflow *Completed this study step*.	Maternal Interview Call (Attachment 4)	301	1	1
Mother, POP workflow *Completed this study step*.	Self-Administered Forms (Attachment 6a–e, 6f or 6g, 6h–i, 6k, 6n–p).	267	1	105/60
Mother, POP workflow *Completed this study step*.	Follow-up Call 2 (Attachment 14)	267	1	20/60
Mother, POP workflow *Completed this study step*.	Developmental Assessment saliva collection (Attachment 8a–d), overall consent (Attachment 15c).	234	1	50/60
Father, POP workflow *Completed this study step*.	Clinic/Home Visit—Saliva Collection (Attachments 8b–d).	117	1	15/60
Child, POP workflow *Completed this study step*.	Clinic/Home Visit—Developmental Assessment Attachment 7a–c), saliva collection (Attachment 8a–d).	234	1	90/60
Mother, DD workflow *All potential participants sent mailing*.	Invitation Packet/Response Card (Attachments 10b, 10e, and 10g).	641	1	10/60
Mother, DD workflow *Potentially eligible with contact by study staff*.	Invitation Call Script (Attachment 11b) and SCQ (Attachment 3).	321	1	30/60
Mother, DD workflow *Eligible, consented, and enrolled; assigned to the DD workflow based on enrollment intake*.	Enrollment Packet (Attachment 12b–d)	175	1	20/60
Mother, DD workflow *Completed this study step*.	Follow-up Phone Call Script (Attachment 13) and Checklist and Pregnancy Reference Form (Attachments 5a and 5b).	158	1	15/60
Mother, DD workflow *Completed this study step*.	Maternal Interview Call (Attachment 4)	158	1	1
Mother, DD workflow *Completed this study step*.	Self-Administered Forms (Attachments 6a–d, 6j, 6m, and 6o–p).	140	1	55/60
Mother, DD workflow *Completed this study step*.	Follow-up Call 2 (Attachment 15b)	140	1	20/60

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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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10709]

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 November 29, 2019.

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 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.*

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–10709 Hospital Survey for Specified Covered Outpatient Drugs (SCODs)

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Hospital Survey for Specified Covered Outpatient Drugs (SCODs); *Use:* In the CY 2018 OPPS/ASC payment system final rule with comment period, CMS finalized a policy to adjust payment for separately payable outpatient drugs acquired by eligible hospitals at discounted rates under HRSA's 340B program from Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. According to 42 U.S.C. 256b, eligible hospitals include those with a Medicare Disproportionate Share Hospital adjustment of greater than 11.75 percent, Children's Hospitals, Critical Access Hospitals, Cancer Hospitals, Rural Referral Centers and Sole Community Hospitals. The 340B program sets a ceiling on the price that covered entities pay for outpatient drugs. The 340B ceiling price refers to the maximum amount that a manufacturer can charge a covered entity for the purchase of a 340B covered outpatient drug. The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA).

On December 27, 2018, the United States District Court for the District of Columbia ruled that the Secretary of the Department of Health & Human Services exceeded his statutory authority to adjust payment rates under the Hospital Outpatient Prospective Payment System (OPPS) for separately payable, 340B-acquired drugs. *See American Hospital Ass'n* v. *Azar,* 348 F. Supp. 3d 62, 82–83 (D.D.C. 2018), *appeal pending,* Nos. 19–5048 & 19–5198 (D.C. Cir.). The Court reasoned, in part, that the Secretary had not collected the necessary data to set payment rates based on acquisition costs. The government disagrees with that ruling and has appealed. Nonetheless, in the event that the ruling is affirmed, CMS believes that it is important to begin obtaining acquisition costs for specified covered outpatient drugs to set payment rates based on cost for 340B-acquired drugs when they are furnished by certain covered entity hospitals.

The acquisition cost data hospitals submit in response to this survey will be used to help determine payment amounts for drugs acquired under the 340B program. We want to ensure that the Medicare program pays for specified covered outpatient drugs purchased under the 340B program at amounts that approximate what hospitals actually pay to acquire the drugs. This will ensure that the Medicare program uses taxpayer dollars prudently while maintaining beneficiary access to these drugs and allowing beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs. *Form Number:* CMS–10709 (OMB control number: 0938–New); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profits, State, Local, or Tribal Governments; *Number of Respondents:* 761; *Total Annual Responses:* 46,610,448; *Total Annual Hours:* 33,484. (For policy questions regarding this collection contact Steven Johnson at 410–786–3332.)

Dated: September 25, 2019.

William N. Parham, III,

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

[FR Doc. 2019–21120 Filed 9–26–19; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3383–N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.