4—PREGNANCY REGISTRY

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
State and Local Health Departments	Maternal Health History Form	100	5	30/60	250
	Specimen Collection Form	100	1	15/60	25
Clinicians and other providers	Assessment at Delivery Form	100	1	30/60	50
	Infant Health Follow-Up Form	100	1	30/60	50
Total					400

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–10113 Filed 4–29–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–131 and CMS–R–244]

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

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 any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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 1, 2016.

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: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov.*

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 *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
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: Reports Clearance Office at (410) 786–1326.

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:* Extension of a currently approved collection; *Title of Information Collection:* Advance Beneficiary Notice of Noncoverage (ABN); *Use:* The Advance Beneficiary Notice (ABN) is delivered by Part B paid physicians, providers (including institutional providers like outpatient hospitals), practitioners (such as chiropractors), and suppliers, as well as hospice providers and Religious Non-medical Health Care Institutions paid under Part A. Home health agencies providing items and services under Part A or Part B also use the ABN. Other Medicare institutional providers paid under Part A use other approved notices for this purpose. With this PRA submission, minimal formatting changes have been made to the ABN form, including the addition of language informing beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 (Section 504) by alerting the beneficiary to CMS's nondiscrimination practices and the availability of alternate forms of this notice, if needed. Additionally, minor language and grammatical changes have been made to the form's instructions to improve provider/supplier comprehension and decrease the probability of errors in completing the ABN. There are no substantive changes to the form or to the instructions. *Form Number:* CMS–R–131 (OMB control number: 0938–0566); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 1,540,850; *Total Annual Responses:* 63,601,300; *Total Annual Hours:* 7,420,364. (For policy questions regarding this collection contact Evelyn Blaemire at 410–786–1803.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The PACE Organization (PO) Application Process in 42 CFR part 460; *Use:* In general, Programs of All-Inclusive Care for the Elderly (PACE) services are provided through a PO. An entity wishing to

become a PO must submit an application to CMS that describes how the entity meets all the requirements in the PACE program. An entity's application must be accompanied by an assurance from the State Administering Agency (SAA) of the State in which the PO is going to be located.

Beginning in 2016, initial PACE applications will be submitted via a new automated, electronic submission process. An application also must be submitted for a PO that seeks to expand its service area and/or add a new PACE center site.

The purpose of this PRA package is to enable the submission of both initial PACE applications, as well as service area expansion applications. We have successfully transitioned the Medicare Advantage application and Prescription Drug Plan (PDP) application to a fully electronic submission process, enabling a more organized and streamlined review, and would like to bring those same efficiencies to all PACE application processes. OMB approval would help ensure applicant compliance with CMS' requirements and ability to gather data used to support approval or denial of either an initial PACE application or a service area expansion application submitted by an existing PO. *Form Number:* CMS–R–244 (OMB control number: 0938–0790); *Frequency:* Once and occasionally; *Affected Public:* Private sector (Not-for-profit institutions); *Number of Respondents:* 730; *Total Annual Responses:* 55,060; *Total Annual Hours:* 5,748. (For policy questions regarding this collection contact Debbie Vanhoven at 410–786–6625.)

Dated: April 27, 2016.

William N. Parham, III,

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

[FR Doc. 2016–10231 Filed 4–29–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–367 and CMS–10243]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 require; 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 any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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 1, 2016

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' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

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: Reports Clearance Office at (410) 786–1326.

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–367 Medicaid Drug Program—Monthly and Quarterly Drug Reporting Format

CMS–10243 Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool

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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Program—Monthly and Quarterly Drug Reporting Format; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto the CMS–64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. *Form Number:* CMS–367 (OMB control number: 0938–0578); *Frequency:* Monthly and Quarterly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 610;