

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Adult at least 18 years old using a private well for tap water.	Screening Form	2,500	1	6/60	250
	Questionnaire	2,000	1	35/60	1,167
	Urine Specimen and Tap Water Sample Collection.	2,000	1	20/60	667
Total	2,084

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-359/360, CMS-10003, and CMS-10280]

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: 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 April 11, 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 information collection; **Title of Information Collection:** Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations; **Use:** The form CMS-359 is used as the application for health care providers seeking to participate in the Medicare program as a Comprehensive Outpatient Rehabilitation Facility (CORF). This form initiates the process for facilities to become certified as a CORF and it provides the CMS Regional Office State Survey Agency staff identifying information regarding the applicant that is stored in the Automated Survey Processing Environment (ASPEN) system.

The form CMS-360 is a survey tool used by the State Survey Agencies to record information in order to determine a provider's compliance with the CORF Conditions of Participation (CoPs) and to report this information to the Federal government. The form includes basic information on the CoP requirements, check boxes to indicate the level of compliance, and a section for recording notes. We have the responsibility and authority for certification decisions which are based on provider compliance with the CoPs and this form supports this process. **Form Number:** CMS-359/360 (OMB control number: 0938-0267); **Frequency:** Occasionally; **Affected Public:** Private Sector (Business or other for-profits); **Number of Respondents:** 50; **Number of Responses:** 50; **Total Annual Hours:** 123. (For questions regarding this collection contact James Cowher (410) 786-1948.)

2. Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Notice of Denial of Medical Coverage (or Payment); **Use:** Medicare health plans, including

Medicare Advantage plans, cost plans, and Health Care Prepayment Plans, are required to issue the CMS-10003 form when a request for either a medical service or payment is denied in whole or in part. The notice explains why the plan denied the service or payment and informs Medicare enrollees of their appeal rights. The notice is also used, as appropriate, to explain Medicaid appeal rights to full dual eligible individuals enrolled in a Medicare health plan that is also managing the individual's Medicaid benefits. The PRA package has been revised subsequent to the publication of the 60-day **Federal Register** notice (October 16, 2015; 80 FR 62534). *Form Number:* CMS-10003 (OMB control number: 0938-0829). *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 730; *Total Annual Responses:* 33,574,293; *Total Annual Hours:* 5,593,477. (For policy questions regarding this collection contact Staci Paige at 410-786-2045.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Home Health Change of Care Notice (HHCCN); *Use:* The Home Health Change of Care Notice (HHCCN) is used to notify original Medicare beneficiaries receiving home health care benefits of plan of care changes. Home health agencies (HHAs) must provide the HHCCN whenever they reduce or terminate a beneficiary's home health services due to physician/provider orders or limitation of the HHA in providing the specific service. Notification is required for covered and non-covered services listed in the plan of care. This iteration contains non-substantive changes which add language informing beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 by alerting the beneficiary to CMS' nondiscrimination practices and the availability of alternate forms of this notice if needed. There are no substantive changes. *Form Number:* CMS-10280 (OMB control number: 0938-0829); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 12,459; *Total Annual Responses:* 13,764,434; *Total Annual Hours:* 917,262. (For policy questions regarding this collection contact Evelyn Blaemire at 410-786-1803).

Dated: March 7, 2016.

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-10146, CMS-10377, CMS-10465 and CMS-10409]

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 any of the following subjects: 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 May 10, 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-10146 Notice of Denial of Medicare Prescription Drug Coverage
 CMS-10377 Student Health Insurance Coverage
 CMS-10465 Minimum Essential Coverage
 CMS-10409 Long Term Care Hospital (LCTH) Continuity Assessment Record and Evaluation (CARE) Data Set

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.