

Incontinence
 Dyspareunia
 Castleman Disease
 Gestational Carrier
 Third Degree Laceration
 Ectopic Pregnancy
 Initial Encounter and Surveillance for vaginal ring
 hormonal contraceptive device and transdermal patch
 hormonal contraceptive device
 Ovarian Cyst Laterality
 Supervision of Pregnancy with History of Ectopic or Molar Pregnancy
 National Institute of Health Stroke Scale
 Irritable Bowel Syndrome
 Chronic Idiopathic Constipation
 ICD-10-CM Addendum

Agenda items are subject to change as priorities dictate.

Note: CMS and NCHS will no longer provide paper copies of handouts for the meeting. Electronic copies of all meeting materials will be posted on the CMS and NCHS Web sites prior to the meeting at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage and http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm.

Contact Persons for Additional Information: Donna Pickett, Medical Systems Administrator, Classifications and Public Health Data Standards Staff, NCHS, 3311 Toledo Road, Room 2413, Hyattsville, Maryland 20782, email dfp4@cdc.gov, telephone 301-458-4434 (diagnosis); Mady Hue, Health Insurance Specialist, Division of Acute Care, CMS, 7500 Security Boulevard, Baltimore, Maryland 21244, email marilu.hue@cms.hhs.gov, telephone 410-786-4510 (procedures).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Gary Johnson,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-1856 and CMS-1893, and CMS-10380]

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 September 24, 2014.

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:* Revision of a currently approved collection; *Title of Information Collection:* (CMS-1856) Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services, and (CMS-1893) Outpatient Physical Therapy—Speech Pathology Survey Report; *Use:* Form CMS-1856 is used as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare and Medicaid programs. This form initiates the process for obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy, speech-language pathology services, or both. It is used by the State agencies to enter new providers into the Automated Survey Process Environment (ASPEN). Form CMS-1893 is used by the State survey agency to record data collected during an on-site survey of a provider of outpatient physical therapy and/or speech-language pathology services, to determine compliance with the applicable conditions of participation, and to report this information to the Federal government. The form is

primarily a coding worksheet designed to facilitate data reduction and retrieval into the ASPEN system. The information needed to make certification decisions is available to us only through the use of information abstracted from the form.

Form Numbers: CMS-1856 and CMS-1893 (OMB control number: 0938-0065); *Frequency:* Annually, occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 700; *Total Annual Responses:* 700; *Total Annual Hours:* 613. (For policy questions regarding this collection contact James Cowher at 410-786-1948.)

2. Type of Information Collection Request: Revision of a currently approved collection; **Title of Information Collection:** Reporting Requirements for Grants to States for Rate Review Cycle I, Cycle II, Cycle III, and Cycle IV and Effective Rate Review Program; **Use:** Under the section 1003 of the Affordable Care Act (ACA) (section 2794 of the Public Health Service Act), the Secretary, in conjunction with the states and territories, is required to establish a process for the annual review, beginning with the 2010 plan year, of unreasonable increases in premiums for health insurance coverage. Section 2794(c) requires the Secretary to establish the Rate Review Grant Program to states to assist states to implement this provision. In addition, section 2794(c) requires the Rate Review Grant Program to assist states in the establishment and enhancement of “Data Centers” that collect, analyze, and disseminate health care pricing data to the public.

Concurrent with this information collection request (ICR), HHS released Cycle IV of the Rate Review Grants, “Grants to States to Support Health Insurance Rate Review and Increase Transparency in the Pricing of Medical Services.” The purpose of Cycle IV of the Rate Review Grant Program is to continue the rate review successes of Cycles I, II, and III, as well as to provide greater support to Data Centers, thereby enhancing medical pricing transparency. States and territories that apply for funds are required to complete the grant application. States and territories that are awarded funds under this funding opportunity are required to provide the Secretary with rate review data, four quarterly reports, and one annual report per year until the end of the grant period detailing the state’s progression towards a more comprehensive and effective rate review process. A final report is due at the end of the grant period. This information

collection is required for effective monitoring of grantees and to fulfill statutory requirements under section 2794(b)(1)(A) of the ACA that requires grantees, as a condition of receiving a grant authorized under section 2794(c), to report to the Secretary information about premium increases.

On May 23, 2011, CMS published a final rule with comment period (76 FR 29964) to implement the annual review of unreasonable increases in premiums for health insurance coverage called for by section 2794. Under the regulation, if CMS determines that a state has an Effective Rate Review Program in a given market, using the criteria set forth in the rule, CMS will adopt that state’s determinations regarding whether rate increases in that market are unreasonable, provided that the state reports its final determinations to CMS and explains the bases of its determinations. The final rule titled “Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review” (78 FR 13406; February 27, 2013) amends the standards under the Effective Rate Review Program. Currently, CMS relies on publicly available information and annual calls with individual states to obtain the information needed to evaluate whether a state has begun to or continues to satisfy the Effective Rate Review Program criteria. CMS is proposing to instead collect the information in writing from all states that would like to request effective status. No comments were received in response to the 60-day **Federal Register** notice published on June 2, 2014 (79 FR 31336). *Form Number:* CMS-10380 (OMB control number: 0938-1121); *Frequency:* Annually and On occasion; *Affected Public:* Public Sector and State and Territory Governments; *Number of Respondents:* 50; *Total Annual Responses:* 553; *Total Annual Hours:* 20,951. (For policy questions regarding this collection contact Susie Lorden at 301-492-4162.)

Dated: August 19, 2014.

Martique Jones,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2014-20041 Filed 8-22-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0501]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 24, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0643. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE-14526, Silver Spring, MD 20993-0002 PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Third Party Disclosure and Recordkeeping Requirements for Reportable Food—21 U.S.C. 350f (OMB Control Number 0910-0643)—Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) requires the establishment of a Reportable Food Registry (the Registry) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. Section 417 of the FD&C Act (21 U.S.C. 350f) defines “reportable