ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Laboratorians	National Laboratory Training Network Registration Form (Attachment 3).	6,500	1	5/60

Dated: March 7, 2013.

Ron A. Otten,

Director, 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 Identifier CMS–484, CMS–10152, CMS–10449]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title:* Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Documentation Requirements; *Use:* Under Section 1862(a)(1)(A) of the Social Security Act (the Act), 42 U.S.C. 1395y(a), the Secretary may only pay for items and services that are ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' In order to assure this, CMS and its contractors develop Medical policies that specify the circumstances under which an item or service can be covered. The certificate of medical necessity (CMN) provides a mechanism for suppliers of Durable Medical Equipment, defined in 42 U.S.C. 1395x (n), and Medical Equipment and Supplies defined in 42 U.S.C. 1395j(5), to demonstrate that the item being provided meets the criteria for Medicare coverage. Section 1833(e), 42 U.S.C. 1395l(e), provides that no payment can be made to any provider of services, or other person, unless that person has furnished the information necessary for Medicare or its contractor to determine the amounts due to be paid. Certain individuals can use a CMN to furnish this information, rather than having to produce large quantities of medical records for every claim they submit for payment. Under Section 1834(j)(2) of the Act, 42 U.S.C. 1395m(j)(2), suppliers of DME items are prohibited from providing medical information to physicians when a CMN is being completed to document medical necessity. The physician who orders the item is responsible for providing the information necessary to demonstrate that the item provided is reasonable and necessary and the supplier shall also list on the CMN the fee schedule amount and the suppliers charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician. Any supplier of medical equipment who knowingly and willfully distributes a CMN in violation of this restriction is subject to penalties, including civil money penalties (42 U.S.C. 1395m(j)(2)(A)(iii)). Under title 42 of the Code of Federal Regulations, §§ 410.38 and 424.5, Medicare has the legal authority to collect sufficient information to determine payment for oxygen, and oxygen equipment. Oxygen and oxygen equipment is by far the largest single total charge of all items paid under durable medical equipment coverage authority. Detailed criteria concerning coverage of home oxygen therapy are found in Medicare Carriers Manual Chapter II—Coverage Issues Appendix, Section 60–4. For Medicare to consider any item for coverage and payment, the information submitted by the supplier (e.g., claims and CMNs), including documentation in the patient's medical records must corroborate that the patient meets Medicare coverage criteria. The patient's medical records may include: physician's office records; hospital records; nursing home records; home health agency records; records from other healthcare professionals or test reports. This documentation must be available to the DME MACs upon request. *Form Number:* CMS–484 (OCN: 0938–0534); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits, Not-for-profits; *Number of Respondents:* 8,880; *Total Annual Responses:* 1,541,359; *Total Annual Hours:* 308,271. (For policy questions regarding this collection contact Doris Jackson at 410–786–4459. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title:* Data Collection for Medicare Beneficiaries Receiving NaF–18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer; *Use:* In Decision Memorandum #CAG–00065R, issued on February 26, 2010, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving NaF–18 PET scan to identify bone metastasis in cancer is reasonable and necessary only when the provider is participating in and patients are enrolled in a clinical study designed to information at the time of the scan to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all

Medicare enrolled patients; and all patient confidentiality, privacy, and other Federal laws must be followed. Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meets specified standards and address the specified research questions. To qualify for payment, providers must prescribe certain NaF–18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. The statuary authority for this policy is section 1862(a)(1)(E) of the Act. The need to prospectively collect information at the time of the scan is to assist the provider in decision making for patient management. *Form Number:* CMS–10152 (OCN: 0938–0968); *Frequency:* Annual; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 25000; *Total Annual Responses:* 25000; *Total Annual Hours:* 2,084 hours. (For policy questions regarding this collection contact Stuart Caplan at 410–786–8564. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Revision; *Title of Information Collection:* Recognized Accrediting Entities Data Collection; *Use:* The final rule that was released on July 20, 2012 (77 FR 42658) establishes a process for recognizing accrediting entities for the purposes of implementing section 1311(c)(1)(D)(i) of the Affordable Care Act. In order for a health plan to be certified as a QHP and operate in an Exchange, it must be accredited by an accrediting entity that has been recognized by the Secretary of Health and Human Services. The final rule establishes the first phase of a two-phased process for recognition of accrediting entities. In phase one, the National Committee for Quality Assurance (NCQA) and URAC were recognized as accrediting entities for the purposes of fulfilling the accreditation requirement as part of qualified health plan certification. In a subsequent final rule, released February 22, 2013, we amended the first phase of this process to allow additional accrediting entities to apply to be recognized. The assessment used to assess these additional accrediting entities will be the same as the assessment underlying the recognition of NCQA and URAC. This information collection is necessary to ensure that the recognized accrediting entities meet the proposed conditions. 45 CFR 156.275(c) requires that the accrediting entities provide accreditation survey data elements, including accreditation status, accreditation score, accreditation expiration date, clinical quality measure results and adult and child CAHPS measure survey results to the Exchanges once these data are released by the issuers. Further, accrediting entities applying to be recognized must provide to HHS the accreditation standards and requirements, processes, and measure specifications for performance measures and, once recognized, any proposed changes or updates to these standards, and requirements, processes and measure specifications with 60-day notice prior to public notification. This collection, which is approved under OCN: 0938–1176), is necessary in order for Exchanges to verify that the QHPs being offered in their Exchange meet the accreditation requirement and are high quality plans.

The 60-day **Federal Register** notice published on November 23, 2012 (77 FR 70163). We received two comments. The comments concerned issuer burden associated with the data collection and the content of the data submission. These comments were addressed in full in the Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule. Generally, we noted that this data collection pertained to the submission of data from accrediting entities seeking to be recognized and accrediting entities already recognized, rather than issuers. Comments related to the content of the data submission were deemed out of scope. *Form Number:* CMS–10449; *Frequency:* Monthly, Occasionally; *Affected Public:* Private sector, Not-for-profit institutions; *Number of Respondents:* 4; *Number of Responses:* 60; *Total Annual Hours:* 3,544. (For policy questions regarding this collection contact Rebecca Zimmermann at (301) 492–4396. For all other issues, call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *April 15, 2013:* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: March 8, 2013.

Martique Jones,

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

[FR Doc. 2013–05802 Filed 3–13–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 18, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *ACRHD@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously