DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10381, CMS–484, CMS–10152 and CMS–R–290]

Agency Information Collection Activities: Proposed Collection; 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:* Revision of a currently approved collection; *Title:* ICD–10 Industry Readiness Assessment; *Use:* The Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, enacted on August 21, 1996. Through subtitle F of title II of HIPAA, the Congress added to title XI of the Social Security Act (the Act) a new Part C, entitled ''Administrative Simplification.'' Part C of title XI of the Act now consists of sections 1171 through 1180, which define various terms and impose several requirements on HHS, health plans, health care clearinghouses, and certain health care providers concerning the transmission of health information. Specifically, HIPAA requires the Secretary of HHS to adopt standards that covered entities are required to use in conducting certain health care administrative transactions, such as claims, remittance, eligibility, and claims status requests and responses. Findings from the ICD–10 industry readiness assessment will be used by CMS to understand each sector's progress toward compliance and to determine what communication and educational efforts can best help affected entities obtain the tools and resources they need to achieve timely compliance with ICD–10. Insights gleaned from the proposed research will be valid for education and outreach purposes only, and will not be used for policy purposes. *Form Number:* CMS–10381 (OCN: 0938–1149); *Frequency:* Annual; *Affected Public:* Private Sector—Business or other for-profits, Not-for-profits; *Number of Respondents:* 1,200; *Total Annual Responses:* 1,200; *Total Annual Hours:* 204. (For policy questions regarding this collection contact Rosali Topper at 410–786–7260. For all other issues call 410–786–1326.)

2. *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 Section 42 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.)

3. *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 Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that the CMS determines meet 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 Social Security 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:* 25,000; *Total Annual Responses:* 25,000; *Total Annual Hours:* 2,084. (For policy questions regarding this collection contact Stuart Caplan at 410–786–8564. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Reinstatement of a currently approved collection; *Title:* Medicare Program: Procedures for Making National Coverage Decisions; *Use:* The Centers for Medicare & Medicaid Services (CMS) revised the April 27, 1999 (64 FR 22619) notice and published a new notice on September 26, 2003 (68 FR 55634) that described the process we use to make Medicare coverage decisions including decisions regarding whether new technology and services can be covered. We have made changes to our internal procedures in response to the comments we received following publication of the 1999 notice and experience under our new process. Over the past several years, we received numerous suggestions to further revise our process to continue to make it more open, responsive, and understandable to the public. We share the goal of increasing public participation in the development of Medicare coverage issues. This will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. *Form Number:* CMS–R–290 (OCN: 0938–0776); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 8,000. (For policy questions regarding this collection contact Katherine Tillman at 410–786–9252. 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.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *October 9, 2012:*

1. *Electronically.* You may submit 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) 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.

Dated: August 7, 2012.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0781]

Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representative on the Pediatric Advisory Committee and Request for Nominations for Nonvoting Industry Representatives on the Pediatric Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Pediatric Advisory Committee for the Office of the Commissioner (OC) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the Pediatric Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by September 10, 2012, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by September 10, 2012.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Walter Ellenberg (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 301–796–0885, FAX: 301–847–8640, *walter.ellenberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. OC Advisory Committee

Pediatric Advisory Committee

The Committee reviews and evaluates and makes recommendations to the Commissioner of Food and Drugs