

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
Statement of Organization, Functions, and Delegations of Authority; Office of the National Coordinator for Health and Information Technology; Correction

AGENCY: Office of the Secretary, HHS.

ACTION: Notice, correction.

SUMMARY: This Notice was previously published in the **Federal Register** on December 1, 2009, but it contained an error with respect to one of the office names.

FOR FURTHER INFORMATION CONTACT:

Marc Weisman, Office of the National Coordinator, Office of the Secretary, 200 Independence Ave., NW., Washington, DC 20201, 202-690-6285.

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Chapter AR, Office of the National Coordinator for Health Information Technology (ONC), as last amended at 74 FR 62785-62786, dated December 1, 2009, is corrected as follows:

I. Under Section AR.10 Organization, retitle "B. Office of Economic Modeling and Analysis (ARB)" as B. Office of Economic Analysis and Modeling (ARB)."

II. Under Section AR.20 Functions, Chapter B, retitle all references to the "Office of Economic Modeling and Analysis" as the "Office of Economic Analysis and Modeling."

III. Delegation of Authority. Pending further delegation, directives or orders by the Secretary or by the National Coordinator for Health Information Technology, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101.)

Dated: July 26, 2010.

Kathleen Sebelius,
Secretary.

[FR Doc. 2010-19999 Filed 8-12-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

[Document Identifier: CMS-265-94, CMS-1728-94, CMS-10240, CMS-P-0015A and CMS-10203]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506I(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, 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 function; (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:* Extension of a currently approved collection; *Title of Information Collection:* Independent Renal Dialysis Facility Cost Report; *Use:* The Independent Renal Dialysis Facility Cost Report, is filed annually by providers participating in the Medicare program to identify the specific items of cost and statistics of facility operation that independent renal dialysis facilities are required to report. *Form Number:* CMS-265-94 (OMB#: 0938-0236); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 5,508 *Total Annual Responses:* 5,508; *Total Annual Hours:* 275,400 (For policy questions regarding this collection contact Gail Duncan at 410-786-7278. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Home Health Agency Cost Report; *Use:* These cost report forms are filed annually by freestanding providers participating in the Medicare program to effect year end cost settlement for providing services to

Medicare beneficiaries. The data submitted on the cost reports supports management of Federal programs. Providers receiving Medicare reimbursement must provide adequate cost data based on financial and statistical records which can be verified by qualified auditors. The data from these cost reporting forms will be used for the purpose of evaluating current levels of Medicare reimbursement. *Form Number:* CMS-1728-94 (OMB#: 0938-0022); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 7,479 *Total Annual Responses:* 7,479; *Total Annual Hours:* 1,690,254 (For policy questions regarding this collection contact Angela Havrilla at 410-786-4516. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection for the Nursing Home Value-Based Purchasing (NHVBP) Demonstration; *Use:* The goal of the NHVBP Demonstration is to use financial incentives to improve the quality of care in nursing homes. The main purpose of the NHVBP data collection effort is to gather information that will enable CMS to determine which nursing homes will be eligible to receive incentive payments under the NHVBP Demonstration. Information will be collected from nursing homes participating in the demonstration on an ongoing basis. CMS will collect payroll-based staffing, agency staffing and resident census information to help assess the quality of care in participating nursing homes. CMS will determine which homes qualify for an incentive payment based on their relative performance in terms of quality. *Form Number:* CMS-10240 (OMB#: 0938-1039); *Frequency:* Quarterly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 178 *Total Annual Responses:* 712; *Total Annual Hours:* 5,530 (For policy questions regarding this collection contact Ron Lambert at 410-786-6624. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey; *Use:* The Medicare Current Beneficiary Survey (MCBS) serves to measure what impact the changes of adding a new benefit have on the program and its beneficiaries. The MCBS is a comprehensive data collection effort that fills an information gap in the

Centers for Medicare and Medicaid Services, and is depended on to help manage the program. Being able to examine various characteristics and to chart evolving trends offers policy makers a reliable tool for making informed decisions. The MCBS is used to identify potential new policy direction or modifications to the Medicare program and once those program enhancements are implemented, monitor the impact of those changes. The central goals of the MCBS are to determine medical care expenditures and sources of payment for all services, including copayments, deductibles, and non-covered services; to ascertain all types of health insurance coverage and relate coverage to actual payments; and to trace processes over time, such as changes in health status, spending down to Medicaid eligibility, and the impacts of program changes. *Form Number:* CMS-P-0015A (OMB#: 0938-0568); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 16,217 *Total Annual Responses:* 48,650; *Total Annual Hours:* 57,062 (For policy questions regarding this collection contact William Long at 410-786-7927. For all other issues call 410-786-1326.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Health Outcomes Survey (HOS); *Use:* CMS has a responsibility to its Medicare beneficiaries to require that care provided by managed care organizations under contract with CMS is of high quality. One way of ensuring high quality care in Medicare Managed Care Organizations (MCOs), or more commonly referred to as Medicare Advantage Organizations (MAOs), is through the development of standardized, uniform performance measures to enable CMS to gather the data needed to evaluate the care provided to Medicare beneficiaries.

The goal of the Medicare HOS program is to gather valid, reliable, clinically meaningful health status data in Medicare managed care for use in quality improvement activities, plan accountability, public reporting, and improving health. All managed care plans with Medicare Advantage (MA) contracts must participate. CMS, in collaboration with the National Committee for Quality Assurance (NCQA), launched the Medicare HOS as part of the Effectiveness of Care component of the former Health Plan Employer Data and Information Set, now known as the Healthcare

Effectiveness Data and Information Set (HEDIS®).

The HOS measure was developed under the guidance of a Technical Expert Panel comprised of individuals with specific expertise in the health care industry and outcomes measurement. The measure includes the most recent advances in summarizing physical and mental health outcomes results and appropriate risk adjustment techniques. In addition to health outcomes measures, the HOS is used to collect the Management of Urinary Incontinence in Older Adults, Physical Activity in Older Adults, Fall Risk Management, and Osteoporosis Testing in Older Women HEDIS® measures. The collection of Medicare HOS is necessary to hold Medicare managed care contractors accountable for the quality of care they are delivering. This reporting requirement allows CMS to obtain the information necessary for proper oversight of the Medicare Advantage program. *Form Number:* CMS-10203 (OMB#: 0938-0701); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 1,099,560 *Total Annual Responses:* 1,099,560; *Total Annual Hours:* 366,520 (For policy questions regarding this collection contact Chris Haffer at 410-786-8764. 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 e-mail 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 *September 13, 2010*.

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395-6974, *E-mail:* OIRA_submission@omb.eop.gov.

Dated: August 6, 2010.

Michelle Shortt,

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

[FR Doc. 2010-19756 Filed 8-12-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0248]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

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 13, 2010.

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 e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0340. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, Elizabeth.Berbakos@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.

Format and Content Requirements for Over-the-Counter Drug Product Labeling—OMB Control Number 0910-0340—Reinstatement

In the **Federal Register** of March 17, 1999 (64 FR 13254) (the 1999 labeling final rule), we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed over-the-counter (OTC) drug products in part 201 (21 CFR part 201). The regulations in part 201 require OTC drug product labeling to include uniform headings