

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:* Skilled Nursing Facility Resident Assessment MDS Data and Supporting Regulations in 42 CFR 413.337, 413.343, 424.32, and 483.20; *Form Number:* CMS-R-250 (OMB#: 0938-0739); *Use:* Skilled Nursing Facilities (SNFs) are required to submit the resident assessment data as described at 42 CFR 483.20 in the manner necessary to administer the payment rate methodology described in 42 CFR 413.337. Pursuant to sections 4204(b) and 4214(d) of Omnibus Budget Reconciliation Act (OBRA) 1987, the current requirements related to the submission and retention of resident assessment data for the 5th, 30th, 60th and 90th days following admission, necessary to administer the payment rate methodology described in 42 CFR 413.337, are subject to the Paperwork Reduction Act. The burden associated with information collection is the sum of the SNF staff time required to complete the Minimum Data Set (MDS), SNF staff time to encode the data, and SNF staff time spent in transmitting the data.; *Frequency:* Reporting—Other, 5th, 14th, 30th, 60th, and 90th days of stay; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 15,352; *Total Annual Responses:* 4,719,118; *Total Annual Hours:* 3,284,247.

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/regulations/prd/>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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 at the address below, no later than 5 p.m. on March 7, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 28, 2005.

**Michelle Shortt,**

*Director, Regulations Development Group,  
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-10165 and CMS-10149]**

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

**AGENCY:** Centers for Medicare & Medicaid Services.

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), 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:* Application for Participation in the Medicare Care Management Performance Demonstration; *Form Number:* CMS-10165 (OMB#: 0938-0965); *Use:* The Medicare Care Management Performance (MCMP) Demonstration and its corresponding Report to Congress are mandated by the section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Section 649 of the MMA provides for the implementation of a "pay for performance" demonstration under which Medicare would pay incentive payments to physicians who (1) adopt and use health information technology; and (2) meet established standards on clinical performance

measures. This demonstration will be held in four States, Arkansas, California, Massachusetts, and Utah. Providers that are enrolled in the Doctors' Office Quality—Information Technology (DOQ-IT) project are eligible to participate in the demonstration. To enroll in the MCMP Demonstration, a physician/provider must submit an application form. The information collected will be used to assess eligibility for the demonstration; *Frequency:* Reporting—One-time only; *Affected Public:* Business or other for-profit; *Number of Respondents:* 800; *Total Annual Responses:* 800; *Total Annual Hours:* 133.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Health Insurance Reform: Security Standards Final Rule; *Form Number:* CMS-10149 (OMB#: 0938-0949); *Use:* The Department of Health and Human Services (HHS) Medicare Program, other Federal agencies operating health plans or providing health care, State Medicaid agencies, private health plans, health care providers, and health care clearinghouses must assure their customers (for example, patients, insured individuals, providers, and health plans) that the integrity, confidentiality, and availability of electronic protected health information they collect, maintain, use, or transmit is protected. The confidentiality of health information is threatened not only by the risk of improper access to stored information, but also by the risk of interception during electronic transmission of the information. The use of the security standards will improve the Medicare and Medicaid programs, other Federal health programs, and private health programs; in addition, it will improve the effectiveness and efficiency of the health care industry in general by establishing a level of protection for certain electronic health information.; *Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 4,000,000; *Total Annual Responses:* 4,000,000; *Total Annual Hours:* 64,539,263.

To obtain copies of the supporting statement and any related forms for these 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 February 6, 2006.

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 28, 2005.

**Michelle Shortt**,

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### Privacy Act of 1974; Report of a New System of Records

**AGENCY:** Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

**ACTION:** Notice of a new System of Records (SOR).

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new SOR titled, "Medicare Bariatric Surgery System (MBSS), System No. 09-70-0570." National coverage determinations (NCDs) are determinations made by the Secretary of HHS with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act (the Act) section 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," section 1862(a)(1)(A). CMS has determined that the evidence is adequate to conclude that bariatric surgery is reasonable and necessary in several patient groups where certain criteria for these patients have been met. The reasonable and necessary determination requires that patients

meet the MBSS criteria set forth in the decision memorandum and are consistent with the trials discussed. Bariatric surgery is reasonable and necessary only when facilities performing the surgery have full accreditation based on standards equivalent to or exceeding the CMS minimum standards. Collection of data elements related to bariatric surgery allows that determination to be made.

The purpose of this system is to provide reimbursement for bariatric surgery, and assist in the collection of data on patients receiving bariatric surgery, for a data collection process to assure patient safety and protection, and to determine that the bariatric surgery is reasonable and necessary. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) assist an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in certain Federally-funded health benefits programs. We have provided background information about the modified system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See **EFFECTIVE DATES** section for comment period.

**EFFECTIVE DATE:** CMS filed a new SOR report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on 12/29/2005. We will not disclose any information under a routine use until 30 days after publication. We may defer implementation of this system or one or more of the routine use statements listed

below if we receive comments that persuade us to defer implementation.

**ADDRESSES:** The public should address comment to the CMS Privacy Officer, Mail Stop N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.-3 p.m., eastern daylight time.

#### FOR FURTHER INFORMATION CONTACT:

Rosemarie Hakim, Epidemiologist, Office of Clinical Standards and Quality, CMS, Mail Stop C1-09-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1849. She may be contacted via telephone at (410) 786-3934, or via e-mail at *Rosemarie.Hakim@cms.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Obesity is a growing epidemic in the United States with over 60% of the population classified as overweight or obese. One form of treatment for obesity is bariatric surgery. In May 2005 CMS began a reconsideration of the NCD on BS for Medicare beneficiaries submitted by the American Society for bariatric surgery, the American Obesity Association, and others. The requestors included the following bariatric surgery procedures in their request for reconsideration: (1) Roux-en-y Gastric Bypass, (2) Biliopancreatic Diversion, (3) Laparoscopic Adjustable Gastric Banding, and (4) Vertical Gastric Banding. CMS has determined that the evidence is adequate to conclude that bariatric surgery is reasonable and necessary for Medicare beneficiaries who have a Body Mass Index  $\geq 35$ , at least one co-morbidity related to morbid obesity, and have been unsuccessful with medical treatment for obesity.

#### I. Description of the Proposed System of Records

##### A. Statutory and Regulatory Basis for SOR

The statutory authority for linking coverage decisions to the collection of additional data is derived from section 1862(a)(1)(A) of the Act, which states that Medicare may not provide payment for items and services unless they are "reasonable and necessary" for the treatment of illness or injury. In some cases, CMS will determine that an item or service is only reasonable and necessary when specific data collections accompany the provisions of the service. In these cases, the collection of data is required to ensure that the care provided to individual patients will improve health outcomes.