DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–249, CMS–10238, CMS–102, 105, CMS–10243 and CMS–10244]

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:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Cost and Data Report and supporting regulations 42 CFR 413.20 and 42 CFR 413.24; *Use:* In accordance with sections 1815(a), 1833(e), 1861(v)(A)(ii) and 1881(b)(2)(B) of the Social Security Act, providers of services in the Medicare program are required to submit annual information to receive reimbursement for health care services provided to Medicare beneficiaries. In addition, 42 CFR 413.20(b) requires that cost reports be filed with the provider's fiscal intermediary/Medicare Administrative Contractor (FI/MAC). The functions of the FI/MAC are described in section 1816 of the Social Security Act. The Center for Medicare and Medicaid Services will use the information from providers for rate evaluations for the Prospective Payment System. *Form Number:* CMS–R–249 (OMB#: 0938–0758); *Frequency:* Reporting: Yearly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 1938; *Total Annual Responses:* 1938; *Total Annual Hours:* 341,088.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Testing of Revised OASIS Instrument for Home Health Quality Measures & Data Analysis; *Use:* Medicare-certified home health agencies (HHAs) must meet the Conditions of Participation (COPs) as set forth at 42 CFR part 484 and 488. Since 1999, the COPs have mandated that HHAs use the ''Outcome and Assessment Information Set'' (OASIS) data set when evaluating adult, non-maternity patients receiving skilled services. The OASIS is a patient-specific, comprehensive assessment that identifies each patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs.

Since OASIS data collection was mandated in 1999, CMS has been systematically collecting input on ways to improve the OASIS instrument and reduce the burden of the collection effort. In 2002, CMS introduced the ''reduced-burden'' OASIS that was a product of the Secretary's Regulatory Reform Advisory Committee to help guide HHS' broader efforts to streamline unnecessarily burdensome or inefficient regulations that interfere with the quality of health care. Since the 2002 revision, CMS has continued to solicit input on potential refinements and enhancements of the OASIS instrument from HHAs, industry associations, consumer representatives, researchers and other stakeholders.

Abt Associates and their subcontractor UCHSC were awarded a contract by CMS in September 2006 to continue the process of refining the OASIS data set, as well as for the testing of the instrument and analysis of the impact of proposed changes. Under this contract, researchers from Abt Associates, University of Colorado Health Sciences Center (UCHSC), and Case Western Reserve University have assisted CMS in carrying out the revisions based on the input described in the previous section. Changes to the OASIS instrument include the following removal and revision of items:

- Elimination of 7 original OASIS items not required for payment, quality or risk adjustment;
- Replacement of 44 original OASIS items with items that are revised and/or simplified to respond to industry concerns by increasing clarity and user-friendliness, and/or reducing complexity and burden (e.g., removal of ''prior status'' assessment for all Activity of Daily Living (ADL) and Instrumental Activity of Daily Living (IADL) items).

The revised OASIS also includes the addition of the following process items to support evidence-based practices:

- A total of 7 process items to be collected only at Start of Care/Resumption of Care, 4 of which are to be asked seasonally (e.g.; flu vaccine);
- A total of 10 process items to be collected only at Follow-up, Transfer or Discharge, either seasonally or on a small subpopulation;
- A total of 13 process items to be collected at all OASIS time points, 6 of which are to be collected on a small subpopulation.

We estimate the elimination, simplification and revision of existing OASIS items will have a burden impact equivalent to the complete elimination of 19 items. Since many of the process items will be collected only on small subpopulations or during specific months of the year, we estimate the impact of the addition of these items on burden to be equivalent to the addition of 20 items. Therefore, total impact of proposed OASIS revisions, including the elimination, revision and addition of items, changes the estimated burden of the OASIS very little while incorporating process measures needed to support evidence-based practices across the post-acute care spectrum. *Form Number:* CMS–10238 (OMB#: 0938–NEW); *Frequency:* Reporting: One-time; *Affected Public:* Private Sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 11; *Total Annual Responses:* 11; *Total Annual Hours:* 173.58.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendment (CLIA) Budget Workload Reports and Supporting Regulations Contained in 42 CFR 493.1–.2001; *Use:* Information collected will be used by CMS in determining the amount of Federal Reimbursement for compliance surveys. Use of the information includes program evaluation, audit, budget formulation and budget approval; *Form Number:* CMS–102, 105 (OMB#: 0938–0599); *Frequency:* Reporting: Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 550; *Total Annual Hours:* 4,500.

4. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument; *Use:* The Medicare Continuity Assessment Record and Evaluation (CARE) is a uniform

patient assessment instrument designed to measure differences in patient severity, resource utilization, and outcomes for patients in acute and post-acute care settings. This tool will be used to (1) Standardize program information on Medicare beneficiaries' acuity at discharge from acute hospitals, (2) document medical severity, functional status and other factors related to outcomes and resource utilization at admission, discharge, and interim times during post acute treatment, and (3) understand the relationship between severity of illness, functional status, social support factors, and resource utilization. The CARE instrument will be used in the Post-Acute Care (PAC) Payment Reform Demonstration program mandated by Section 5008 of the Deficit Reduction Act of 2005 to develop payment groups that reflect patient severity and related cost and resource use across post acute settings. Specifically, the data collected using the CARE instrument during the Post-Acute Care Payment Demonstration will be used by CMS to develop a setting neutral post-acute care payment model as mandated by Congress. The data will be used to characterize patient severity of illness and level of function in order to predict resource use, post-acute care discharge placement, and beneficiary outcomes. CMS will use the data from the CARE instrument to examine the degree to which the items on the instrument can be used to predict beneficiary resource use and outcomes. *Form Number:* CMS–10243 (OMB#: 0938–NEW); *Frequency:* Reporting—Daily; *Affected Public:* Private Sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 388; *Total Annual Responses:* 244,292; *Total Annual Hours:* 179,341.

5. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Medicaid State Program Integrity Assessment (SPIA); *Use:* Under the provisions of the Deficit Reduction Act (DRA) of 2005, Congress directed CMS to establish the Medicaid Integrity Program (MIP), CMS' first national strategy to combat Medicaid fraud, waste, and abuse. CMS has two broad responsibilities under the MIP:

(1) Reviewing the actions of individuals or entities providing services or furnishing items under Medicaid; conducting audits of claims submitted for payment; identifying overpayments; and educating providers and others on payment integrity and quality of care; and

(2) Providing effective support and assistance to States to combat Medicaid fraud, waste, and abuse.

In order to fulfill the second of these requirements, CMS plans to develop a Medicaid State Program Integrity Assessment (SPIA) system. CMS is seeking approval from the Office of Management and Budget (OMB) to collect information from the States on an annual basis for input into a national SPIA system. Through the SPIA system, CMS will identify current Medicaid program integrity (PI) information, develop profiles for each State based on these data, determine areas to provide States with technical support and assistance, and use the data to develop performance measures to assess States' performance in an ongoing manner; *Form Number:* CMS–10244 (OMB#: 0938–NEW); *Frequency:* Reporting: Yearly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,400.

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 at the address below, no later than 5 p.m. on September 25, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L. Harkless, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 18, 2007.

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–R–312]

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:* Extension of a currently approved collection; *Title of Information Collection:* Conflict of Interest and Ownership and Control Information *Use:* The Conflict of Interest and Ownership and Control Information Statement (COI Statement) is sent to all Medicare Fiscal Intermediaries (FIs) and Carriers to collect full and complete information on any entity's or individual's ownership interest (defined as a 5 per centum or more) in an organization that may present a potential conflict of interest in their role as a Medicare FI or Carrier.

The information gathered in the survey is used to ensure that all potential, apparent and actual conflicts of interest involving Medicare contractors are appropriately mitigated and that employees of the contractors, including officers, directors, trustees and members of their immediate families, do not utilize their positions with the contractor for their own private business interest to the detriment of the Medicare program. Information is also requested on potential organizational conflicts of interest involving Medicare contractors' ownership of other entities in the health care industry. If a response has indicated that a potential conflict of interest exists, the contractor is contacted and asked to address how the conflict can be avoided or mitigated. *Form Number:* CMS–R–312 (OMB#: 0938–0795); *Frequency:* Reporting—Annually; *Affected Public:* Private Sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 37; *Total Annual Responses:* 37; *Total Annual Hours:* 11,100.

To obtain copies of the supporting statement and any related forms for the