

484.11 and 484.20; *Use*: This request is for OMB approval to continue to require home health agencies (HHAs) to electronically report the Outcome and Assessment Information Set (OASIS) data to CMS. OASIS is a requirement of one of the Conditions of Participation (CoP) that HHAs must meet in order to participate in the Medicare program. Specifically, the aforementioned regulation sections provide guidelines for HHAs for the electronic transmission of the OASIS data as well as responsibilities of the State agency or OASIS contractor in collecting and transmitting this information to CMS. These requirements are necessary to achieve broad-based, measurable improvement, in the quality of care furnished through Federal programs, and to establish a prospective payment system for HHAs; *Form Number*: CMS-R-209 (OMB#: 0938-761); *Frequency*: Reporting—Monthly; *Affected Public*: Business or other for-profit, Not-for-profit institutions, Federal government, State, Local, or Tribal governments; *Number of Respondents*: 8,277; *Total Annual Responses*: 102,203; *Total Annual Hours*: 1,374,051.

4. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Medicare and Medicaid Programs OASIS Collection Requirements as Part of the Conditions of Participation for Home Health Agencies and Supporting Regulations in 42 CFR 484.55, 484.205, 484.245, 484.250; *Use*: The Medicare and Medicaid Programs OASIS Collection Requirements as Part of the Conditions of Participation for Home Health Agencies (HHAs) information collection requires HHAs to use a standard core assessment data set, the Outcome and Assessment Information Set (OASIS), to collect information and to evaluate adult non-maternity patients. In addition, data from the OASIS will be used for purposes of case mix adjusting patients under the home health prospective payment system and will facilitate the production of necessary case mix information at relevant time points in the patient's home health stay; *Form Number*: CMS-R-245 (OMB#: 0938-760); *Frequency*: Recordkeeping and Reporting—Other, upon patient assessment; *Affected Public*: Business or other for-profit, Not-for-profit institutions, Federal government, State, Local, or Tribal governments; *Number of Respondents*: 8,277; *Total Annual Responses*: 11,087,565; *Total Annual Hours*: 9,339,184.

5. *Type of Information Collection Request*: New collection; *Title of Information Collection*: Collection of

Medicaid and State Children's Health Insurance (SCHIP) Managed Care Claims and Related Information; *Use*: The Improper Payments Information Act (IPIA) of 2002 (Pub. L. 107-300) requires CMS to produce national error rates in the Medicaid program and the State Children's Health Insurance Program (SCHIP). To comply with the IPIA, CMS will engage a Federal contractor to produce error rates in Medicaid managed care and SCHIP managed care. Beginning in 2007, CMS will use a rotational approach to review up to 18 States for each program, for a total 36 States each year. CMS has completed the State selection process for the Medicaid improper payments measurement. States have not yet been selected for the measurement of improper payments in SCHIP. CMS expects to select the SCHIP States in the fall of 2006; *Form Number*: CMS-10178 (OMB#: 0938-NEW); *Frequency*: Reporting—On occasion, Quarterly; *Affected Public*: State, Local, or Tribal governments; *Number of Respondents*: 36; *Total Annual Responses*: 23,400; *Total Annual Hours*: 23,400.

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](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer:

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395-6974.

Dated: April 4, 2006.

**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-05, CMS-R-72, CMS-10175, CMS 10050, CMS-1957, CMS-1515 & 1572]

### Agency Information Collection Activities: Proposed Collection; 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) 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*: Physician Certifications/Recertifications in Skilled Nursing Facilities (SNFs) Manual Instructions and Supporting Regulations in 42 CFR 424.20; *Use*: Regulations at 42 CFR 424.20 require SNFs to keep record of physician certifications and recertifications of information such as the need for care and services, estimated duration of the SNF stay, and plan for home care. As a condition for Medicare Part A payment for post-hospital skilled nursing facility (SNF) services, the Medicare program requires that a physician certify and periodically recertify that a beneficiary requires an SNF level of care. The physician certification and recertification is intended to ensure that the beneficiary's need for services has been established and then reviewed and updated at appropriate intervals; *Form Number*: CMS-R-05 (OMB#: 0938-0454); *Frequency*: Recordkeeping and Reporting—On occasion; *Affected Public*: State, Local or Tribal governments, Individuals or Households, Business or other for-profit

and Not-for-profit institutions; *Number of Respondents*: 2,458,549; *Total Annual Responses*: 981,642; *Total Annual Hours*: 547,578.

2. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use*: In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed.; *Form Number*: CMS-R-72 (OMB#: 0938-0443); *Frequency*: Reporting—On occasion; *Affected Public*: Individuals or Households and Business or other for-profit institutions; *Number of Respondents*: 2,590; *Total Annual Responses*: 5,228; *Total Annual Hours*: 2,822.

3. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Certification Statement for Electronic File Interchange Organizations (EFIOS) that Submit National Provider Identifier (NPI) Data to the National Plan and Enumeration System; *Use*: The EFI process is designed to allow organizations to submit NPI application information for large numbers of providers in a single file. Once it has obtained and formatted the necessary provider data, the EFIO will electronically submit the file to NPPES for processing. As each file can contain up to approximately 100,000 records, or provider applications, the EFI process greatly reduces the paperwork and overall administrative burden associated with enumerating providers; *Form Number*: CMS-10175 (OMB#: 0938-0984); *Frequency*: Reporting—Other, One-time; *Affected Public*: Business or other for-profit, and Not-for-profit institutions; *Number of Respondents*: 1000; *Total Annual Responses*: 1000; *Total Annual Hours*: 3000.

4. *Type of Information Collection Request*: Extension of a currently

approved collection; *Title of Information Collection*: Survey of Newly Eligible Medicare Beneficiaries; *Use*: CMS is responsible for providing beneficiaries with the Medicare program information they need to effectively choose the health care plan best suited to their needs. In order to provide such information, CMS needs to know (1) Whether or not new enrollees are aware of the choices they have, (2) what beneficiaries understand about the basic elements of the Medicare program, (3) what other sources currently provide Medicare-related information, and (4) how all of these items vary across beneficiary subpopulations. To this end, CMS must have the ability to measure over time what beneficiaries know and understand about the Medicare program. Measuring beneficiaries' information needs and knowledge over time will help CMS evaluate its impact on information/education, population changes and other initiatives; *Form Number*: CMS-10050 (OMB#: 0938-0869); *Frequency*: Reporting—Quarterly; *Affected Public*: Individuals or Households; *Number of Respondents*: 2400; *Total Annual Responses*: 2400; *Total Annual Hours*: 800.

5. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: SSO Report of State Buy-in Problem and Supporting Regulations in 42 CFR 407.40; *Use*: Under the State Buy-In program, States enroll certain groups of needy people under the Part B Supplementary Medical Insurance (SMI) Program and pay their premiums. The purpose of the "buy-in" is to allow the States to provide SMI protection to certain groups of needy individuals as part of its total assistance plan. Generally, States "buy-in" for individuals who are categorically needy under Medicaid and meet the eligibility requirements for Medicare Part B. States can also include in their buy-in agreement those eligible for medical assistance only. The CMS-1957 is used in the resolution of beneficiary complaints regarding State buy-in. This form facilitates the coordination of efforts between the SSO, State Medicaid Agencies, and CMS in the resolution of a beneficiary's State buy-in problem; *Form Number*: CMS-1957 (OMB#: 0938-0035); *Frequency*: Reporting—On occasion; *Affected Public*: Federal government, Individuals or Households, and State, Local, and Tribal governments; *Number of Respondents*: 6,600; *Total Annual Responses*: 6,600; *Total Annual Hours*: 2,366.

6. *Type of Information Collection Request*: Extension of a currently

approved collection; *Title of Information Collection*: Home Health Agency Survey and Deficiencies Report, Home Health Functional Assessment Instrument and Supporting Regulations in 42 CFR 488.26 and 442.30; *Use*: In order to participate in the Medicare program as a Home Health Agency (HHA) provider, the HHA must meet Federal Standards. These forms used to record information about patients' health and provider compliance with requirement and report information to the Federal Government; *Form Number*: CMS-1515 & 1572 (OMB#: 0938-0355); *Frequency*: Reporting—Annually; *Affected Public*: Business or other for-profit, Individuals or Households, and Not-for-profit institutions; *Number of Respondents*: 24,150; *Total Annual Responses*: 24,150; *Total Annual Hours*: 3,864.

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](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 June 13, 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: April 4, 2006.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0107]

### Food and Drug Administration-Regulated Products Containing Nanotechnology Materials; Planning of Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Request for comments.