community/background/AHICsuccessor.html.

Dated: August 20, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10241, CMS–382, CMS–10247, and CMS–10246]

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:* New Collection.

Title of Information Collection: Annual State Report and Annual State Performance Rankings.

Use: The Deficit Reduction Act of 2005 (DRA) requires CMS to contract with a vendor to conduct a monthly national survey of retail prescription drug prices and to report the prices to the States. These national average prices will be used as a benchmark by the States for the management of their prescription drug programs. The law also requires that States report their drug utilization rates for noninnovator multiple source drugs, their payment rates under their State plan, and their dispensing fees. A template will be used to facilitate data collection. The States' rankings are to be presented to the Congress and the States.

Form Number: CMS–10241 (OMB#: 0938–NEW).

Frequency: Reporting—Yearly.

Affected Public: States, Local or Tribal Governments.

Number of Respondents: 51.

Total Annual Responses: 51.

Total Annual Hours: 765.

2. *Type of Information Collection Request:* Extension without change of a currently approved collection.

Title of Information Collection: ESRD Beneficiary Selection and Supporting Regulations Contained in 42 CFR 414.330.

Use: Section 2145 amended section 1881 of the Social Security Act and changes the way the Medicare program pays for home dialysis services. Medicare patients who currently receive dialysis in a facility but later become home dialysis patients must complete the CMS–382 form at the time they go to the home setting. Facilities are required to have all Medicare home dialysis patients choose one of two payment methods. Under Method I, the dialysis facility assumes responsibility for patient care and the facility provides all dialysis equipment and supplies needed to dialyze at home. The facility is required to order, store, deliver, and pay the manufacturers and suppliers for these items. Under Method II, the beneficiary makes his/her own arrangement for securing the necessary supplies and dialysis equipment. Then, the supplier bills the Medicare program (Carrier) for payment.

Form Number: CMS–382 (OMB#: 0938–0372).

Frequency: Reporting—Yearly.

Affected Public: Individuals or households.

Number of Respondents: 7400.

Total Annual Responses: 7400.

Total Annual Hours: 617.

3. *Type of Information Collection Request:* New collection.

Title of Information Collection: Sponsor application for CMS coverage under the Medicare Clinical Trial Research Policy.

Use: The Centers for Medicare & Medicaid Services (CMS) has supported the participation of beneficiaries in clinical research through its Clinical Trial Policy implemented through the National coverage determination (NCD) process since 2000. Support for participation in clinical research studies is provided through the coverage of items and services that are considered usual patient care. Usual patient care encompasses all items and services covered by the program for any beneficiary, i.e., reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member.

In accordance with the Clinical Trial Policy/Clinical Research Policy (CTP/CRP), CMS requires study sponsors/principal investigators to meet a set of standards to (1) Ensure that all sponsors and investigators conduct clinical research so that Medicare covered items and services are reasonable and necessary to obtain valid research outcomes and for treating research participants, and (2) maximize the health outcomes (and minimize risk) for Medicare beneficiaries.

One of the standards states, ''The clinical research study is registered on the ClinicalTrials.gov Web site by the study sponsor/principal investigator prior to the enrollment of the first study subject.'' In practice, we anticipate that study sponsors/principal investigators wishing to have their research study listed as certified on our Web site, and in the **Federal Register** will register the study on ClinicalTrials.gov and complete a form to CMS describing the scope and nature of the clinical research, discussing each of the standards in this policy, and certifying that all standards in this policy have been met. CMS will only review this form for completeness. We are seeking OMB approval for the form.

Form Number: CMS–10247 (OMB#: 0938–New).

Frequency: Reporting—one-time.

Affected Public: Private Sector—Business or other for-profits and not-for-profit institutions.

Number of Respondents: 4,524.

Total Annual Responses: 4,524.

Total Annual Hours: 4,524.

4. *Type of Information Collection Request:* New collection.

Title of Information Collection: Cost and Resource Utilization (CRU) Data Collection for the Medicare Post Acute Care Payment Reform Demonstration.

Use: The CRU data collection is part of the Post-Acute Care Payment Reform Demonstration mandated by Section 5008 of the Deficit Reduction Act of 2005. This demonstration is intended to address problems with the current Medicare payment systems for post-acute care services, including those for Long Term Care Hospitals, Inpatient Rehabilitation Facilities, Skilled Nursing Facilities, and Home Health Agencies. Each of these four types of providers currently has a separate prospective payment system (PPS) with its own case-mix groups, payment units, and rates. Each case-mix grouper uses a unique set of items to measure patients,

making it difficult to compare severity, costs, and outcomes across settings. These four provider types form a continuum of care where patients may overlap in terms of the conditions being treated, but they primarily differ in terms of the severity of the patients' medical or functional impairments. The current payment methods are designed as silos that do not recognize the potential overlap in case mix or the complimentary nature of the services across an episode, nor does it allow for standardized measures of costs across settings since each PPS was developed independently using different measurement systems and underlying assumptions.

The Post-Acute Care Payment Reform Demonstration will examine the relative costliness and outcomes of post acute cases admitted to different settings for similar conditions. The work will differ from past attempts in this area because it will use a standardized case mix tool for measuring patient severity and a standardized resource data collection tool in all four post acute settings. Specifically, the legislation requires that CMS provide information on both the fixed and variables costs for each individual treated in post acute care settings.

The CRU data collection instruments are designed to collect a provider's routine costs to specific patients because in general, nurses' and many other direct care providers' time spent on behalf of specific patients and on activities not patient-specific, is not reported. In addition, charges for therapist services reported on claims may not sufficiently measure true relative differences in therapy resource costs among patients. The data will be used, along with Medicare claims and cost report data, to examine substitution issues: How do costs and outcomes differ for post acute care patients with similar case mix acuity when treated in one of the various settings. The results will be used to provide CMS and Congress information on setting-neutral payment models, revisions to single setting payment systems, current discharge placement patterns, and patient outcomes across settings.

Form Number: CMS–10246 (OMB#: 0938–New).

Frequency: Reporting and Recordkeeping.

Affected Public: Private Sector—Business or other for-profits and not-for-profit institutions.

Number of Respondents: 138.

Total Annual Responses: 61,589.

Total Annual Hours: 28,783.

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 October 23, 2007.

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: August 17, 2007.

Michelle Shortt,

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

[FR Doc. E7–16805 Filed 8–23–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–216, CMS–R–262, CMS–10106, and CMS–10173]

Agency Information Collection Activities: Submission for OMB Review; 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), 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: Issuance of Advisory Opinions Concerning Physicians' Referrals.

Use: Section 1877(g)(6) of the Social Security Act (the Act), requires that the Department of Health and Human Services issue advisory opinions concerning whether the referral of a Medicare patient by a physician for certain designated health services (other than clinical laboratory services) is prohibited under the physician referral provisions of the Social Security Act. Section 1877(g)(6) of the Act requires that the Department of Health and Human Services accept requests for advisory opinions made after November 3, 1997 and before August 21, 2000. Section 543 of the Benefits Improvement and Protection Act of 2001, Public Law 106–554, extended indefinitely the period during which the Department of Health and Human Services accepts requests for these advisory opinions. The collection of information contained in 42 CFR 411.372 and 411.373 is necessary to comply with this statutory mandate, and allow CMS to consider requests for advisory opinions and provide accurate and useful opinions.

Form Number: CMS–R–216 (OMB#: 0938–0714).

Frequency: Once.

Affected Public: Business or other for-profit and Not-for-profit institutions.

Number of Respondents: 50.

Total Annual Responses: 50.

Total Annual Hours: 1,000.

2. *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP).

Use: CMS requires that MA and PDP organizations submit a completed formulary and PBP as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. To see the comprehensive list of changes from CY2007 to CY2008, please refer to the document entitled ''Appendix B—PBP-Formulary CY2008 List of Changes.''

Form Number: CMS–R–262 (OMB#: 0938–0763).

Frequency: Yearly.

Affected Public: Business or other for-profit and Not-for-profit institutions.

Number of Respondents: 450.

Total Annual Responses: 4725.