DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10326, CMS-10487, CMS-P-0015A, CMS-R-10, CMS-R-240, CMS-10282, CMS-R-65 and CMS-10491]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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.

DATES: Comments must be received by **[insert date 60 days after date of publication in the Federal Register]**:

ADDRESSES: When commenting, please reference the document identifier or OMB control

number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at http://www.cms.hhs.gov/PaperworkReductionActof1995.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10326	Electronic Submission of Medicare Graduate Medical Education (GME) Affiliation Agreements
CMS-10487	Medicaid Emergency Psychiatric Demonstration (MEPD) Evaluation
CMS-P-0015A	Medicare Current Beneficiary Survey
CMS-R-10	Advance Directives (Medicare and Medicaid) and Supporting Regulations
CMS-R-240	Prospective Payments for Hospital Outpatient Services and Supporting Regulations
CMS-10282	Conditions of Participation for Comprehensive Outpatient Rehabilitation Facilities (CORFs) and supporting regulations
CMS-R-65	Final Peer Review Organizations Sanction Regulations in 42 CFR Sections 1004.40, 1004.50, 1004.60, and 1004.70
CMS-10491	Enrollment Assistance Program

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal

Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Electronic Submission of Medicare Graduate Medical Education (GME) Affiliation Agreements; Use: We use the information contained in electronic affiliation agreements as documentation of the existence of Medicare GME affiliations, and to verify that the affiliations being formed by teaching hospitals for the purposes of sharing their Medicare Graduate Medical Education FTE cap slots are valid according to CMS regulations. The affiliation agreements are also used as reference materials when potential issues involving specific affiliations arise. Form Number: CMS–10326 (OCN: 0938-1111); Frequency: Yearly; Affected Public: Private sector - Business or other for-profits and Not-for-profit institutions; Number of Respondents: 125; Total Annual Responses: 125; Total Annual Hours: 166. (For policy questions regarding this collection contact Tzvi Hefter at 410-786-0614.)

2. Type of Information Collection Request: New Collection (Request for a new OMB control number); Title of Information Collection: Medicaid Emergency Psychiatric Demonstration (MEPD) Evaluation**;** Use: Since the inception of Medicaid, inpatient care provided to adults ages 21 to 64 in institutions for mental disease (IMDs) has been excluded from federal matching funds. The Emergency Medical Treatment and Active Labor Act (EMTALA), however, requires IMDs that participate in Medicare to provide treatment for psychiatric emergency medical conditions (EMCs), even for Medicaid patients for whose

services cannot be reimbursed. Section 2707 of the Affordable Care Act (ACA) directs the Secretary of Health and Human Services to conduct and evaluate a demonstration project to determine the impact of providing payment under Medicaid for inpatient services provided by private IMDs to individuals with emergency psychiatric conditions between the ages of 21 and 64. We will use the data to evaluate the Medicaid Emergency Psychiatric Demonstration (MEPD) in accordance with the ACA mandates. This evaluation in turn will be used by Congress to determine whether to continue or expand the demonstration. If the decision is made to expand the demonstration, the data collected will help to inform both CMS and its stakeholders about possible effects of contextual factors and important procedural issues to consider in the expansion, as well as the likelihood of various outcomes. Form Number: CMS-10487 (OCN: 0938-NEW); Frequency: Annually; Affected Public: Individuals and households; State, Local and Tribal governments; Business and other for-profits and Not-for-profits; Number of Respondents: 93; Total Annual Responses: 1,944; Total Annual Hours: 2,046. (For policy questions regarding this collection contact Negussie Tilahun at 410-786-2058.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Current Beneficiary Survey; Use: We are the largest single payer of health care in the United States. With full implementation of the Affordable Care Act of 2010 (ACA), the agency will play a direct or indirect role in administering health insurance coverage for more than 120 million people across the Medicare, Medicaid, CHIP, and Exchange populations. One of our critical aims is to be an effective steward, major force, and trustworthy partner in leading the transformation of the health care system. We also aim to

provide Americans with high quality care and better health at lower costs through improvement. At the forefront of these initiatives is the newly formed Center for Medicare and Medicaid Innovation (CMMI).

CMMI is authorized by Section 1115A of the Social Security Act, as established by section 3021 of the ACA and was established to "test innovative payment and service delivery models to reduce program expenditures…while preserving or enhancing the quality of care furnished" to Medicare, Medicaid and CHIP beneficiaries. Implicit across all of CMMI activities is an emphasis on diffusion – finding and validating innovative models that have the potential to scale, facilitating rapid adoption, and letting them take root in organizations, health systems, and communities across America.

The Medicare Current Beneficiary Survey (MCBS) is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through our operations. The MCBS is an in-person, nationally-representative, longitudinal survey of Medicare beneficiaries that we sponsor and is directed by the Office of Information Products and Data Analytics (OIPDA) in partnership with the CMMI. The survey captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (e.g. fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 20 years (encompassing over 1 million interviews), and consists of three annual interviews per survey participant.

The MCBS continues to provide unique insight into the Medicare program and helps both us and our external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries. Form Number: CMS-P-0015A (OCN: 0938–0568); Frequency: Occasionally; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 16,550; Total Annual Responses: 49,650; Total Annual Hours: 58,450 (For policy questions regarding this collection contact William Long at 410-786-7927.)

4. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Advance Directives (Medicare and Medicaid) and Supporting Regulations; Use: The advance directives requirement was enacted because Congress wanted individuals to know that they have a right to make health care decisions and to refuse treatment even when they are unable to communicate. Steps have been taken at both the federal and state level, to afford greater opportunity for the individual to participate in decisions made concerning the medical treatment to be received by an adult patient in the event that the patient is unable to communicate to others, a preference about medical treatment. The individual may make his preference known through the use of an advance directive, which is a written instruction prepared in advance, such as a living will or durable power of attorney. This information is documented in a prominent part of the individual's medical record. Advance directives as described in the Patient Self-Determination Act have

increased the individual's control over decisions concerning medical treatment. Sections 4206 of the Omnibus Budget Reconciliation Act of 1990 defined an advance directive as a written instruction recognized under State law relating to the provision of health care when an individual is incapacitated (those persons unable to communicate their wishes regarding medical treatment).

All states have enacted legislation defining a patient's right to make decisions regarding medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Participating hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care, hospices, religious nonmedical health care institutions, and prepaid or eligible organizations (including Health Care Prepayment Plans (HCPPs) and Medicare Advantage Organizations (MAOs) such as Coordinated Care Plans, Demonstration Projects, Chronic Care Demonstration Projects, Program of All Inclusive Care for the Elderly, Private Fee for Service, and Medical Savings Accounts must provide written information, at explicit time frames, to all adult individuals about: a) the right to accept or refuse medical or surgical treatments; b) the right to formulate an advance directive; c) a description of applicable State law (provided by the State); and d) the provider's or organization's policies and procedures for implementing an advance directive. Form Number: CMS-R-10 (OCN: 0938–0610); Frequency: Yearly; Affected Public: Business or other for-profits; Number of Respondents: 39,575; Total Annual Responses: 39, 575; Total Annual Hours: 2,836,441. (For policy questions regarding this collection contact Sonia Swancy at 410-786-8445.)

5. Type of Information Collection Request: Extension of a currently approved collection. Title of Information Collection: Prospective Payments for Hospital Outpatient Services and Supporting Regulations; Use: The Secretary is required to establish a prospective payment

system (PPS) for hospital outpatient services. Successful implementation of an outpatient PPS (OPPS) requires that we distinguish facilities or organizations that function as departments of hospitals from those that are freestanding. In this regard, we will be able to determine: which services should be paid under the OPPS, the clinical laboratory fee schedule, or other payment provisions applicable to services furnished to hospital outpatients. Information from 42 CFR 413.65(b)(3) and (c) reports is needed to make these determinations. Additionally, hospitals and other providers are authorized to impose deductible and coinsurance charges for facility services, but does not allow such charges by facilities or organizations which are not provider-based. This provision requires that we collect information from the required reports so it can determine which facilities are provider-based. Form Number: CMS-R-240 (OCN: 0938-0798). Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits and Not-for-profit institutions; Number of Respondents: 905; Total Annual Responses: 500,405; Total Annual Hours: 26,563. (For policy questions regarding this collection contact Daniel Schroder at 410-786-7452.)

6. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Conditions of Participation for Comprehensive Outpatient Rehabilitation Facilities (CORFs) and Supporting Regulations; Use: The Conditions of Participation (CoPs) and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a comprehensive outpatient rehabilitation facility (CORF) qualifies to be awarded a Medicare provider agreement. We believe the health care industry practice demonstrates that the patient clinical records and general content of records are necessary to ensure the well-being and safety of patients and that

professional treatment and accountability are a normal part of industry practice. Form Number: CMS-10282 (OCN: 0938-1091); Frequency: Yearly; Affected Public: Private sector - Business or other for-profit and Not-for-profit institutions; Number of Respondents: 314; Total Annual Responses: 314; Total Annual Hours: 8,076. (For policy questions regarding this collection contact Jacqueline Leach at 410-786-4282.)

7. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Final Peer Review Organizations Sanction Regulations in 42 CFR Sections 1004.40, 1004.50, 1004.60, and 1004.70; Use: The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act (the Act), creating the Utilization and Quality Control Peer Review Organization Program. Section 1156 of the Act imposes obligations on health care practitioners and others who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. The QIOs may allow practitioners or other entities, opportunities to submit relevant information before determining that a violation has occurred. The information collection requirements contained in this information collection request are used by the QIOs to collect the information necessary to make their decision. Form Number: CMS-R-65 (OCN: 0938–0444); Frequency: On occasion; Affected Public: Private sector - Business or other for-profit and Not-for-profit institutions; Number of Respondents: 53; Total Annual Responses: 53; Total Annual Hours: 14,310. (For policy questions regarding this collection contact Coles Mercier at 410-786-2112.)

8. Type of Information Collection Request: New collection (Request for a new OMB

control number); Title of Information Collection: Enrollment Assistance Program; Use: As required by the Affordable Care Act, CMS will implement a grant-based Navigator Program to provide support to targeted communities. However, there will also be a need for broader based enrollment assistance in population centers that we identify in states with Federally-facilitated Marketplaces (FFMs) to provide Health Insurance Marketplace enrollment assistance to populations not covered or targeted by the Navigator Program. The target populations are individual consumers and families eligible to enroll in Qualified Health Plans (QHPs) in population centers we identify. Without such access to in-person enrollment assistance, millions of individuals who will be eligible for health insurance coverage in the Marketplaces might not have access to the direct assistance required to make educated choices on available healthcare options and may therefore be unable to successfully enroll in the Marketplaces. To monitor program effectiveness, the Enrollment Assistance Program will provide weekly, monthly, quarterly and annual reports to us. Form Number: CMS-10491 (OCN: 0938-NEW); Frequency: Weekly, Monthly, Quarterly, Yearly; Affected Public: Private Sector; Number of Respondents: 1; Number of Responses: 84; Total Annual Hours: 554. (For policy questions regarding this collection contact Eliza Bangit at 301-492-4219.)

Dated: July 23, 2013

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

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