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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. This is necessary to ensure compliance with an initiative of the Administration. We are requesting an emergency review under 5 CFR Part 1320(a)(2)(i) because public harm is reasonably likely to result if the normal clearance procedures are followed. The approval of this data collection process is essential to ensuring that Information Security (IS) incidents, which also include Personally Identifiable Information (PII) and Protected Health Information (PHI), are captured within the specified timeframe. In absence of this change, a significant number of incidents will not be detected; therefore causing harm and potential risk to the public's identity with identity fraud.

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Title State Health Insurance Exchange Incident Report; *Use:* We have implemented a Computer Matching Agreement (CMA) with the State-Based Administering Entities (AEs). This agreement establishes the terms, conditions, safeguards, and procedures under which CMS will disclose certain information to the AEs in accordance with the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act (Pub. L. 111–152), which are referred to collectively as the Affordable Care Act (ACA), amendments to the Social Security Act made by the ACA, and the implementing regulations. The AEs, which are state entities administering Insurance Affordability Programs, will use the data, accessed through the CMS Data Services Hub (Hub), to make Eligibility Determinations for Insurance Affordability Programs and certificates of exemption.

The AEs shall report suspected or confirmed incidents affecting loss or suspected loss of PII within one hour of discovery to their designated Center for Consumer Information and Insurance Oversight State Officer who will then notify the affected Federal agency data sources, i.e., Internal Revenue Service, Department of Defense, Department of Homeland Security, Social Security Administration, Peace Corps, Office of Personnel Management and Veterans Health Administration. Additionally, AEs shall contact the office of the appropriate Special Agent-in-Charge, Treasury Inspector General for Tax Administration (TIGTA), and the IRS Office of Safeguards within 24 hours of discovery of any potential breach, loss, or misuse of Return Information. *Form Number:* CMS–10496 (OCN: 0938–New); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 18; *Total Annual Responses:* 936; *Total Annual Hours:* 234.

We are requesting OMB review and approval of this collection by *September 25, 2013,* with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by the noted deadline below.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995* or Email 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.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *September 20, 2013:*

1. *Electronically.* You may submit 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) 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 (CMS–10496), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

and,

OMB Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: August 16, 2013.

Martique Jones,

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

[FR Doc. 2013–20396 Filed 8–20–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–194, CMS–10497 and CMS–10250]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 October 21, 2013.

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. Email 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–R–194 Medicare Disproportionate Share Adjustment Procedures and Criteria and Supporting Regulations

CMS–10497 Evaluation of the Medicare Health Care Quality (MHCQ) Demonstration Evaluation: Focus Group and Interview Protocols

CMS–10250 Hospital Outpatient Quality Reporting (OQR) Program

Under the 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:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare Disproportionate Share Adjustment (DSH) Procedures and Criteria and Supporting Regulations; *Use:* Section 1886(d)(5)(F) of the Social Security Act established the Medicare disproportionate share adjustment (DSH) for hospitals, which provides additional payment to hospitals that serve a disproportionate share of the indigent patient population. This payment is an add-on to the set amount per case that we pay to hospitals under the Medicare Inpatient Prospective Payment System (IPPS).

Under current regulations at 42 CFR 412.106, in order to meet the qualifying criteria for this additional DSH payment, a hospital must prove that a disproportionate percentage of its patients are low income using Supplemental Security Income (SSI) and Medicaid as proxies for this determination. This percentage includes two computations: (1) The ''Medicare fraction'' or the ''SSI ratio'' which is the percent of patient days for beneficiaries who are eligible for Medicare Part A and SSI and (2) the ''Medicaid fraction'' which is the percent of patient days for patients who are eligible for Medicaid but not Medicare. Once a hospital qualifies for this DSH payment, we also determine a hospital's payment adjustment. *Form Number:* CMS–R–194 (OCN: 0938–0691); *Frequency:* Occasionally; *Affected Public:* Private sector—business or other for-profits and not-for-profit institutions; *Number of Respondents:* 800; *Total Annual Responses:* 800; *Total Annual Hours:* 400. (For policy questions regarding this collection contact JoAnne Cerne at 410–786–4530.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Medicare Health Care Quality (MHCQ) Demonstration Evaluation: Focus Group and Interview Protocols; *Use:* The Medicare Health Care Quality (MHCQ) Demonstration was developed to address concerns about the U.S. health care system, which typically fragments care while also encouraging both omissions in and duplication of care. To rectify this situation, Congress has directed us to test major changes to the delivery and payment systems to improve the quality of care while also increasing efficiency across the health care system. This would be achieved through several types of interventions: Adoption and use of information technology and decision support tools by physicians and their patients, such as evidence-based medicine guidelines, best practice guidelines, and shared decision-making programs; reform of payment methodologies; improved coordination of care among payers and providers serving defined communities; measurement of outcomes; and enhanced cultural competence in the delivery of care.

The MHCQ Demonstration programs are designed to examine the extent to which major, multifaceted changes to traditional Medicare's health delivery and financing systems lead to improvements in the quality of care provided to Medicare beneficiaries without increasing total program expenditures. Each demonstration site uses a different approach for changing health delivery and financing systems, but all share the goal of improving the quality and efficiency of medical care provided to Medicare beneficiaries. Focus groups and individual interviews will be conducted at 2 demonstration sites that are active in the demonstration: Gundersen Health System (GHS) and Meridian Health System (MHS).

This MHCQ Demonstration evaluation will include analysis of both quantitative and qualitative sources of information. This multifaceted approach will enable this evaluation to consider a broad variety of evidence for evaluating the nature and impact of each site's interventions. We are seeking approval to conduct in-person focus groups and individual interviews with beneficiaries and their caregivers to inform our evaluation of the MHCQ Demonstration at the GHS and MHS demonstration sites. *Form Number:* CMS–10497 (OCN: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 36; *Total Annual Responses:* 36; *Total Annual Hours:* 108. (For policy questions regarding this collection contact Normandy Brangan at 410–786–6640.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Outpatient Quality Reporting (OQR)

Program; *Use:* Section 109(a) of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109–432) amended section 1833(t) of the Social Security Act by adding a new subsection (17) that affects the payment rate update applicable to Outpatient Prospective Payment System (OPPS) payments for services furnished by hospitals in outpatient settings on or after January 1, 2009. Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for quality measures selected by the Secretary in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act will incur a reduction in their annual payment update (APU) factor to the hospital outpatient department fee schedule by 2.0 percentage points. Sections 1833(t)(17)(C)(i) and (ii) of the Act require the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings. Such measures must reflect consensus among affected parties and, to the extent feasible and practicable, must be set forth by one or more national consensus building entities. The Secretary also has the authority to replace measures or indicators as appropriate and requires the Secretary to establish procedures for making the data submitted available to the public. Such procedures must provide the hospitals the opportunity to review such data prior to public release. Our program established under these amendments is referred to as the Hospital Outpatient Quality Reporting (OQR) Program.

Hospital OQR Program payment determinations are made based on OQR quality measure data reported and supporting forms submitted by hospitals as specified through rulemaking. To reduce burden, a variety of different data collection mechanisms are employed, with every consideration taken to employ existing data and data collection systems. The complete list of measures and data collection forms are organized by type of data collected and data collection mechanism.

The Medicare program has a responsibility to ensure that Medicare beneficiaries receive the health care services of appropriately high quality that are comparable to that received by those under other payers. The Hospital OQR Program seeks to encourage care that is both efficient and of high quality in the hospital outpatient setting through collaboration with the hospital community to develop and implement quality measures that are fully and specifically reflective of the quality of hospital outpatient services. *Form Number:* CMS–10250 (OCN: 0938–1109); *Frequency:* Occasionally; *Affected Public:* Private sector—For-profit and not for institutions; *Number of Respondents:* 3,200; *Total Annual Responses:* 3,200; *Total Annual Hours:* 949,590. (For policy questions regarding this collection contact Anita Bhatia at 410–786–7236.)

Dated: August 16, 2013.

Martique Jones,

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

[FR Doc. 2013–20400 Filed 8–20–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

The Food and Drug Administration/ European Medicines Agency Orphan Product Designation and Grant Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following meeting entitled ''The Food and Drug Administration/European Medicines Agency Orphan Product Designation and Grant Workshop.'' This 1-day workshop is intended to provide valuable information about the FDA and European Medicines Agency (EMA) Orphan Drug Designation programs, the FDA Humanitarian Use Device (HUD) Designation program, and the FDA Orphan Products Grant program to participants representing pharmaceutical, biotechnology, and device companies, as well as academics.

Date and Time: The meeting will be held on October 4, 2013, from 8:30 a.m. to 4 p.m.

Location: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Eleanor Dixon-Terry, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5279, Silver Spring, MD 20993–0002, 301–796–8660, FAX: 301–847–8621, *Eleanor.Dixon-Terry@fda.hhs.gov.*

Registration: Interested participants may register for this meeting at the following Web site: *https://events-support.com/events/FDA_Orphan_Workshop.* If you need sign language interpretation during this meeting, please contact Eleanor Dixon-Terry at *Eleanor.Dixon-Terry@fda.hhs.gov* by September 20, 2013.

Attendance: Online registration for the workshop will be limited to 240 participants for the morning session, of which approximately 50 teams (up to 150 participants) may register for the one-on-one sessions. There will be no registration fee for the workshop.

For participants who cannot attend the morning meetings, simultaneous live interactive Webcasts will be made available. Participants may access the drug and biologics Webcast by visiting the following site: *https://collaboration.fda.gov/odd100413/.* The medical devices Webcast can be accessed by visiting: *https://collaboration.fda.gov/hudd100413/.*

SUPPLEMENTARY INFORMATION: The FDA/EMA Orphan Product Designation and Grant Workshop is being conducted in partnership with the European Organisation for Rare Diseases, Genetic Alliance, and the National Organization for Rare Disorders.

The morning program includes two simultaneous sessions. The first will provide an overview of the FDA and EMA Orphan Drug Designation programs, respectively, while the second will provide an overview of the FDA HUD Designation Program and Pediatric Device Consortia Grant Program. Both morning sessions will also cover the Orphan Products Grant Program as they relate to drugs, biologics, and devices. Both of these morning sessions will also be available by Webcast.

The afternoon session (no Webcast), provides an opportunity for appropriately registered participants to have one-on-one meetings with FDA staff members onsite, to discuss the specifics on how to apply for an orphan product grant, a HUD designation, or orphan drug designation. It also provides for videoconference sessions with EMA staff representatives on EMA orphan drug designation. Participants requesting one-on-one meetings are expected to bring information for at