Billing Code: 4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10394, CMS-10544, CMS-10008, CMS-855I, and CMS-10545]

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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and 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. 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: William Parham at (410) 786-4669.

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-10394 Application to be Qualified Entity to Receive Medicare Data for Performance Measurement

CMS-10544 Good Cause Processes

CMS-10008 Eligibility of Drugs, Biologicals, and Radiopharmaceutical Agents for Transitional Pass-Through Status under the Hospital

CMS-855i Medicare Enrollment Application for Physician and Non-Physician Practitioners

CMS-10545 Outcome and Assessment Information Set (OASIS) OASIS–C2/ICD–10

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 Collection

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Application to be Qualified Entity to Receive Medicare Data for Performance Measurement; Use: The Patient Protection and Affordable Care Act (ACA) was enacted on March 23, 2010 (Pub. L. 111-148). ACA amends section 1874 of the Social Security Act by adding a new subsection (e) to make standardized extracts of Medicare claims data under Parts A, B, and D available to qualified entities to evaluate the performance of providers of services and

suppliers. This is the application needed to determine an organization's eligibility as a qualified entity. To implement the requirements outlined in the legislation, CMS established the Qualified Entity Certification Program (QECP) to evaluate an organization's eligibility across three areas: organizational and governance capabilities, addition of claims data from other sources (as required in the statute), and data privacy and security. This collection covers the application through which organizations provide information to CMS to determine whether they will be approved as a qualified entity. Form Number: CMS-10394 (OMB control number: 0938-1144); Frequency: Reporting-Yearly; Affected Public: Private Sector (State, Local, or Tribal Governments, Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 30; Total Annual Responses: 10; Total Annual Hours: 5,000. (For policy questions regarding this collection contact Kari Gaare at 410-786-8612.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Good Cause Processes; Use: Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D-1(b)(1)(B)(v) of the Act generally directs us to establish rules related to enrollment, dis-enrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. Consistent with these sections of the Act, subpart B in each of the Parts C and D regulations sets forth requirements with respect to involuntary dis-enrollment procedures at 42 C.F.R. §§ 422.74 and 423.44, respectively. In addition, section 1876(c)(3)(B) establishes that individuals may be dis-enrolled from coverage as specified in regulations. Thus, current regulations at 42 C.F.R. 417.460 specify that a cost plan, specifically a Health Maintenance Organization (HMO) or competitive medical plan (CMP), may dis-enroll a member who fails to pay

premiums or other charges imposed by the plan for deductible and coinsurance amounts. Within these regulatory provisions, individuals dis-enrolled for nonpayment of premiums are afforded a grace period in which to request reinstatement. As part of the reinstatement request process, they must demonstrate good cause for failure to pay within the initial grace period that led to their involuntary dis-enrollment and pay all overdue premiums within three calendar months after the dis-enrollment date. Form Number: CMS-10544 (OMB control number: 0938-1271); Frequency: Reporting – Monthly; Affected Public: Private Sector (Business or other for-profit institutions); Number of Respondents: 10,008; Total Annual Responses: 10,008; Total Annual Hours: 6,665. (For policy questions regarding this collection contact Carla Patterson at 410-786-1000).

3. Type of Information Collection Request: Reinstatement with a change of a previously approved collection; Title of Information Collection: Eligibility of Drugs, Biologicals, and Radiopharmaceutical Agents for Transitional Pass-Through Status under the Hospital; Use: Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. As originally enacted by the Balanced Budget Refinement Act (BBRA), this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107-186); current drugs and biological agents and brachytherapy used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. For those drugs and biological agents referred to as "current," the transitional pass-through payment began on the first date the hospital OPPS was implemented (before enactment of Benefits Improvement and Protections Act (BIPA) (Pub. L. 106-554), on December 21, 2000). Transitional pass-through payments are also required for certain "new" drugs, devices and biological agents that were not being paid for as a hospital outpatient department (OPD) service as of December 31, 1996, and

whose cost is "not insignificant" in relation to the outpatient perspective payment system (OPPS) payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years. We have qualified thousands for transitional pass-through payments through our application process. However, to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner as the law intended, it is necessary that we continue to collect appropriate information from interested parties such as hospitals and pharmaceutical companies that bring to our attention specific new drugs, biologicals and radiopharmaceuticals to be evaluated for transitional pass-through status. Form Number: CMS-10008 (OMB control number: 0938-0802); Frequency: Yearly; Affected Public: Private sector (Business or other for-profit institutions); Number of Respondents: 30; Total Annual Responses: 30; Total Annual Hours: 480. (For policy questions regarding this collection contact Raymond Bulls at 410-786-7267).

4. Type of Information Collection Request: New collection (Request for new OMB control number); Title of Information Collection: Medicare Enrollment Application for Physician and Non-Physician Practitioners; Use: The application is used by Medicare contractors to collect data to ensure that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare, including information that allows the Medicare contractor to correctly price, process and pay the applicant's claims. This application collects information to ensure that only legitimate physicians, non-physician practitioners, and other eligible professionals are enrolled in the Medicare program. It is meant to be the first line defense to protect our beneficiaries from illegitimate providers and to protect the Medicare Trust Fund against fraud. It also gathers information that allows Medicare contractors to ensure that the provider/supplier is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, suspended or excluded from any other

Federal agency or program. Form Number: CMS-855I (OMB control number: 0938-NEW); Frequency: On Occasion; Affected Public: State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); Number of Respondents: 513,872; Total Annual Responses: 1,370,078; Total Annual Hours: 1,000,167. (For policy questions regarding this collection contact Kimberly McPhillips at 410-786-5374).

5. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Outcome and Assessment Information Set (OASIS) OASIS–C2/ICD–10; Use: This request is for OMB approval to modify the Outcome and Assessment Information Set (OASIS) that home health agencies (HHAs) are required to collect in order to participate in the Medicare program. The current version of the OASIS, OASIS-C2 (0938-1279) data item set was approved by the Office of Management and Budget (OMB) on December 9, 2016 and implemented on January 1, 2017. We are seeking OMB approval for the proposed revised OASIS item set, referred to hereafter as OASIS-D, scheduled for implementation on January 1, 2019. The OASIS D is being modified to: include changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act); accommodate data element removals to reduce burden; and improve formatting throughout the document. Form Number: CMS-10545 (OMB control number: 0938-1279); Frequency: Occasionally; Affected Public: Private Sector (Business or other for-profit and Not-for-profit institutions); Number of Respondents: 12,149; Total Annual Responses: 18,161,942; Total Annual Hours: 9,943,141. (For policy questions regarding this collection contact Joan Proctor at 410-786-0949).

Dated: March 7, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018-04893 Filed: 3/9/2018 8:45 am; Publication Date: 3/12/2018]