

of Diabetes Educators' (AADE) request for the Secretary's approval of its accreditation program for outpatient DSMT services. The AADE submitted all the necessary materials to enable us to make a determination concerning its request for re-approval as a deeming organization for DSMTs. AADE was initially accredited on August 27, 2012, for a period of 3 years. This application was determined to be complete on February 27, 2015. This notice also solicits public comments on the ability of the AADE to continue to develop standards that meet or exceed the Medicare conditions for coverage and apply them to entities furnishing outpatient.

The regulations specifying the Medicare conditions for coverage for outpatient diabetes self-management training services are located in parts 410, subpart H. These conditions implement section 1861(qq) of the Act, which provides for Medicare Part B coverage of outpatient DSMT services specified by the Secretary.

Under section 1865(a)(2) of the Act and our regulations at § 410.142 (CMS process for approving accreditation organizations) and § 410.143 (Requirements for approved accreditation organizations), we review and evaluate a national accreditation organization based on (but not necessarily limited to) the criteria set forth in § 410.142(b).

We may conduct on-site inspections of a national accreditation organization's operations and office to verify information in the organization's application and assess the organization's compliance with its own policies and procedures. The on-site inspection may include, but is not limited to, reviewing documents, auditing documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

#### IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not

able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document. Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a notice in the **Federal Register** announcing the result of our evaluation.

Dated: April 7, 2015.

**Andrew M. Slavitt**,

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10392 and CMS-10418]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by May 26, 2015.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR*, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

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](mailto: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:** Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Consumer Operated and Oriented (CO-OP) Program; *Use:* The Consumer Operated and Oriented Plan (CO-OP) program was established by Section 1322 of the Affordable Care Act. This program provides for loans to establish at least one consumer-operated, qualified nonprofit health insurance issuer in each State. Issuers supported by the

CO-OP program will offer at least one qualified health plan at the silver level of benefits and one at the gold level of benefits in the individual market State Health Benefit Exchanges (Exchanges). At least two-thirds of policies or contracts offered by a CO-OP will be open to individuals and small employers. Profits generated by the nonprofit CO-OPs will be used to lower premiums, improve benefits, improve the quality of health care delivered to their members, expand enrollment, or otherwise contribute to the stability of coverage offered by the CO-OP. By increasing competition in the health insurance market and operating with a strong consumer focus, the CO-OP program will provide consumers more choices, greater plan accountability, increased competition to lower prices, and better models of care, benefiting all consumers, not just CO-OP members.

The CO-OP program will provide nonprofits with loans to fund start-up costs and State reserve requirements, in the form of Start-up Loans and Solvency Loans. An applicant may apply for (1) joint Start-up and Solvency Loans; or (3) only a Solvency Loan. Planning Loans are intended to help loan recipients determine the feasibility of operating a CO-OP in a target market. Start-up Loans are intended to assist loan recipients with the many start-up costs associated with establishing a new health insurance issuer. Solvency Loans are intended to assist loan recipients with meeting the solvency requirements of States in which the applicant seeks to be licensed to issue qualified health plans. *Form Number:* CMS-10392 (OMB control number 0938-1139); *Frequency:* Occasionally; *Affected Public:* Private Sector (Not-for-profit institutions); *Number of Respondents:* 23; *Total Annual Responses:* 675; *Total Annual Hours:* 93,220. (For policy questions regarding this collection contact Deepti Loharikar at 301-492-4126.)

**2. Type of Information Collection**  
*Request:* Revision of currently approved collection; *Title of Information Collection:* Annual MLR and Rebate Calculation Report and MLR Rebate Notices; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the reinsurance,

risk corridors, and risk adjustment programs established under sections 1341, 1342, and 1343, respectively, of the Affordable Care Act. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). An interim final rule (IFR) implementing the MLR was published on December 1, 2010 (75 FR 74865) and modified by technical corrections on December 30, 2010 (75 FR 82277), which added Part 158 to Title 45 of the Code of Federal Regulations. The IFR is effective January 1, 2011. A final rule regarding selected provisions of the IFR was published on December 7, 2011 (76 FR 76574, CMS-9998-FC) and an interim final rule regarding an issue not included in issuers' reporting obligations (disbursement of rebates by non-federal governmental plans) was also published December 7, 2011 (76 FR 76596, CMS-9998-IFC2). Both rules published on December 7, 2011 are effective January 1, 2012. Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary.

Under Section 1342 of the Patient Protection and Affordable Care Act and implementing regulation at 45 CFR part 153, issuers of qualified health plans (QHPs) must participate in a risk corridors program. A QHP issuer will pay risk corridors charges or be eligible to receive risk corridors payments based on the ratio of the issuer's allowable costs to the target amount. A final rule (Premium Stabilization Rule) implementing the risk corridors program was published on March 23, 2012 (77 FR 17220), which added part 153 to title 45 of the Code of Federal Regulations. The Premium Stabilization Rule is effective May 22, 2012. Final rules (2014 Payment Notice, 2015 Payment Notice, and 2016 Payment Notice) outlining the risk corridors benefit and payment parameters for the 2014, 2015, and 2016 benefit years were published on March 11, 2013 (78 FR 15410), March 11, 2014 (79 FR 13744),

and February 27, 2015 (80 FR 10750), respectively. Additionally, on October 30, 2013, HHS published the Second Final Program Integrity rule (78 FR 65076) to align the risk corridors program with the requirements of the single risk pool provision at 45 CFR 156.80. The risk corridors data collection applies to QHP issuers the individual and small group markets. Each QHP issuer is required to submit an annual report to CMS concerning the issuer's allowable costs, allowable administrative costs, premium, and proportion of market premium in QHPs. Risk corridors premium information that is specific to an issuer's QHPs is collected through a separate data reporting form. CMS is publishing the risk corridors plan-level reporting form, and instructions for completing the form for public comment as part of the proposed revision to this information collection requirement.

On January 30, 2015, CMS published a 60-day notice in the **Federal Register** (80 FR 5118) for the public to submit written comments on this information collection; the public comment period closed on March 31, 2015. As part of the 60-day notice, CMS updated its annual burden hour estimates, including to reflect the additional burden (published in the 2015 Payment Notice) related to the risk corridors data submission requirements. The proposed revisions in the 60-day notice also made changes regarding the new MLR reporting and rebate distribution deadlines and the accounting for the reinsurance, risk adjustment, and risk corridors. We received a total of 3 public comments on a number of specific issues regarding the notice of the revised MLR PRA package. We have taken into consideration all of the comments and has modified the 2014 MLR Annual Reporting Form, the Risk Corridors Plan Level Data Form, and the accompanying Instructions in order to correct minor errors and to provide additional clarifications. These modifications do not affect the previously estimated burden hours or costs. *Form Number:* CMS-10418 (OMB control number: 0938-1164); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 517; *Number of Responses:* 3,307; *Total Annual Hours:* 271,600. (For policy questions regarding this collection, contact Julie McCune at (301) 492-4196.)

Dated: April 21, 2015.  
**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS-9091-N]

**Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January through March 2015**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive

and interpretive regulations, and other **Federal Register** notices that were published from January through March 2015, relating to the Medicare and Medicaid programs and other programs administered by CMS.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone number
I CMS Manual Instructions .....	Ismael Torres .....	(410) 786-1864
II Regulation Documents Published in the <b>Federal Register</b> .....	Terri Plumb .....	(410) 786-4481
III CMS Rulings .....	Tiffany Lafferty .....	(410)786-7548
IV Medicare National Coverage Determinations .....	Wanda Belle .....	(410) 786-7491
V FDA-Approved Category B IDEs .....	John Manlove .....	(410) 786-6877
VI Collections of Information .....	Mitch Bryman .....	(410) 786-5258
VII Medicare –Approved Carotid Stent Facilities .....	Lori Ashby .....	(410) 786-6322
VIII American College of Cardiology-National Cardiovascular Data Registry Sites .....	Marie Casey, BSN, MPH.	(410) 786-7861
IX Medicare’s Active Coverage-Related Guidance Documents .....	JoAnna Baldwin .....	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions .....	JoAnna Baldwin .....	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites .....	Stuart Caplan, RN, MAS.	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities .....	Marie Casey, BSN, MPH.	(410) 786-7861
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities .....	Marie Casey, BSN, MPH.	(410) 786-7861
XIV Medicare-Approved Bariatric Surgery Facilities .....	Jamie Hermansen .....	(410) 786-2064
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials .....	Stuart Caplan, RN, MAS.	(410) 786-8564
All Other Information .....	Annette Brewer .....	(410) 786-6580

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the

authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

**II. Format for the Quarterly Issuance Notices**

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used

as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a Web site proves to be difficult, the contact person listed can provide information.