

Prevention and the Agency for Toxic Substances and Disease Registry.

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[FR Doc. 2015-01768 Filed 1-29-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-R-306, CMS-10371, CMS-10392, CMS-10418, CMS-10472, CMS-10494 and CMS-10549]

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 March 31, 2015.

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-306 Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations
 CMS-10371 Cooperative Agreements to Support Establishment of State-Operated Health Insurance Exchanges
 CMS-10392 Consumer Operated and Oriented (CO-OP) Program
 CMS-10418 Annual MLR and Rebate Calculation Report and MLR Rebate Notices
 CMS-10472 Exchange Functions: Standards for Navigators and Non-Navigator Assistance
 CMS-10494 Standards for Navigators and Non-Navigator Assistance Personnel; Consumer Assistance Tools and Programs of an Exchange and Certified Application Counselors
 CMS-10549 Generic Clearance for Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey (MCBS)

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:* Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations; *Use:* Psychiatric residential treatment facilities are required to report deaths, serious injuries and attempted suicides to the State Medicaid Agency and the Protection and Advocacy Organization. They are also required to provide residents the restraint and seclusion policy in writing, and to document in the residents' records all activities involving the use of restraint and seclusion. *Form Number:* CMS-R-306 (OMB Control Number 0938-0833); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 390; *Total Annual Responses:* 1,466,795; *Total Annual Hours:* 431,062. (For policy questions regarding this collection contact Cindy Ruff at 410-786-5916).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Cooperative Agreements to Support Establishment of State-Operated Health Insurance Exchanges; *Use:* All States (including the 50 States, consortia of States, and the District of Columbia herein referred to as States) had the opportunity under Section 1311(b) of the Affordable Care Act to apply for three types of grants: (1) Planning grants; (2) Early Innovator grants for early development of information technology; and (3) Establishment grants to develop, implement and start-up Marketplaces. As of January 1st, 2015, the Secretary has disbursed over \$5.4 billion under

this grant program and, as of that date, there were 79 active establishment grants awarded to 28 states. As the State-Based Marketplaces (SBM) and Small Business Health Options Program (SHOP) have matured and moved from the developmental phases to full-operation, the reporting requirements for the states have been modified and streamlined to insure only information necessary to provide effective oversight of their operations by CMS is collected. Given the innovative nature of Exchanges and the statutorily-prescribed relationship between the Secretary and States in their development and operation, it is critical that the Secretary work closely with States to provide necessary guidance and technical assistance to ensure that States can meet the prescribed timelines, federal requirements, and goals of the statute and the grants awarded to them. *Form Number:* CMS-10371 (OMB Control Number: 0938-1119); *Frequency:* Once; *Affected Public:* State Government agencies, non-profit entities; *Number of Respondents:* 28; *Number of Responses:* 48; *Total Annual Hours:* 31,404. (For policy questions regarding this collection contact Dena Pushkin at 301-492-4342.)

3. 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 301-492-4126).

4. Type of Information Collection Request: Revision of a currently approved information 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 transitional reinsurance, risk adjustment, and risk corridors. 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 is required to pay charges to or receive payments from CMS 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 and 2015 Payment Notices) outlining the risk corridors benefit and payment parameters for the 2014 and 2015 benefit years were published on March 11, 2013 (78 FR 15410) and March 11, 2014 (79 FR 13744), respectively. The 2014 and 2015 Payment Notices are effective April 30, 2013 and May 12, 2014, respectively. Each QHP issuer is required to submit an annual report to CMS concerning the issuer's allowable costs, allowable administrative costs, and the amount of premium.

Based upon our experience in the MLR data collection and evaluation process, we are updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices. In addition, we are updating its annual burden hour estimates to reflect the additional burden (published in the 2015 Payment Notice) related to the risk corridors data submission requirements.

The 2014 MLR Reporting Form and instructions reflect changes for the 2014 reporting year and beyond that are set forth in the March 2013 update to 45 CFR part 158 regarding the MLR reporting and rebate distribution deadlines and the accounting for the transitional reinsurance, risk

adjustment, and risk corridors. The 2014 MLR Reporting Form and instructions are also modified to include the reporting elements required under the risk corridors data submission requirements in 45 CFR 153.530. In 2015, it is expected that issuers will send fewer notices and rebate checks to policyholders and subscribers, which will reduce burden on issuers. On the other hand, the requirement to report the risk corridors data will increase burden for QHP issuers. It is estimated that there will be a net reduction in total burden from 294,911 to 271,600. *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.)

5. *Type of Information Collection Request:* Revision of a previously approved information collection; *Title of Information Collection:* Patient Protection and Affordable Care Act; Consumer Assistance Tools and Programs of an Exchange and Certified Application Counselors; Exchange and Insurance Market Standards for 2015; *Use:* Section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations have been finalized at 45 CFR 155.215(b)(1) to require Navigators, as well as those non-Navigator personnel to whom 45 CFR 155.215 applies, requires completion of HHS approved training for initial certification and annual recertification prior to providing application and enrollment assistance. The training will include an optional training quality questionnaire providing Navigators and non-Navigator assistance personnel to whom 45 CFR 155.215 applies, an opportunity to provide feedback to CMS regarding the training and any improvements that can be made in the future. *Form Number:* CMS-10472 (OMB Control Number: 0938-1220); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); individuals or households; *Number of Respondents:* 5,610; *Number of Responses:* 5,610; *Total Annual Hours:* 37,036. (For policy questions regarding this collection,

contact Heather Raeburn at 301-492-4224.)

6. *Type of Information Collection Request:* Revision of a previously approved information collection; *Title of Information Collection:* Patient Protection and Affordable Care Act; Consumer Assistance Tools and Programs of an Exchange and Certified Application Counselors; Exchange and Insurance Market Standards for 2015; *Use:* Section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations establishing the certified application counselor program have been finalized at 45 CFR 155.225. In accordance with 155.225(d)(1) and (7), certified application counselors in all Exchanges are required to be initially certified and recertified on at least an annual basis and successfully complete Exchange-required training. *Form Number:* CMS-10494 (OMB Control Number: 0938-1205); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (Not-for-profit institutions); Individuals or Households; *Number of Respondents:* 30,000; *Number of Responses:* 30,000; *Total Annual Hours:* 7,500. (For policy questions regarding this collection, contact Tricia Beckmann at 301-492-4328.)

7. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Generic Clearance for Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey (MCBS); *Use:* The purpose of this OMB clearance package is to clear a Generic Clearance to support an effort to evaluate the operations and content of the Medicare Current Beneficiary Survey (MCBS). The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. The MCBS, which is sponsored by the Centers for Medicare & Medicaid Services (CMS), is the only comprehensive source of information on the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries.

The core of the MCBS is a series of interviews with a stratified random sample of the Medicare population, including aged and disabled enrollees,

residing in the community or in institutions. Questions are asked about enrollees' patterns of health care use, charges, insurance coverage, and payments over time. Respondents are asked about their sources of health care coverage and payment, their demographic characteristics, their health and work history, and their family living circumstances. In addition to collecting information through the core questionnaire, the MCBS collects information on special topics through supplements. For example, questions are asked about enrollees' income and assets, access to health care, health and functional status and satisfaction with care. Special supplements also focus on emerging trends in health care. *Form Number:* CMS-10549 (OMB control number 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,500; *Total Annual Responses:* 1,500; *Total Annual Hours:* 1,117. (For policy questions regarding this collection contact William Long at 410-786-7927.)

Dated: January 27, 2015.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015-01790 Filed 1-29-15; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10530, CMS-1880 and CMS-1882]

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