

the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(4).

Dated: June 28, 2012.

Kathleen Sebelius,
Secretary.

[FR Doc. 2012-16588 Filed 7-5-12; 8:45am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10433, CMS-10438, CMS-10439 and CMS-10440]

Agency Information Collection Activities: Proposed Collection; Comment Request; Webinars

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send 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.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Initial Plan Data Collection to Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations; *Use:* As required by the final rule that published on March 27, 2012 (77 FR 18310), entitled *CMS-9989-F: Establishment of Exchanges and Qualified Health Plans*; Exchange Standards for Employers, each Exchange must assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, essential health benefits, and actuarial value. In order to

meet those standards, the Exchange is responsible for collecting data and validating that QHPs meet these minimum requirements as described in the Exchange rule under 45 CFR 155 and 156, based on the Affordable Care Act, as well as other requirements determined by the Exchange. In addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the Affordable Care Act, detailed in 45 CFR part 153 and in the final rule that published on March 23, 2012 (77 FR 17220) entitled *CMS-9975-F: Standards for Reinsurance, Risk Corridors, and Risk Adjustment*, have general information reporting requirements that apply to non-QHPs outside of the Exchanges. *Form Number:* CMS-10433 (OCN: 0938-New); *Frequency:* Annually; *Affected Public:* States and Private Sector; Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 3400; *Number of Responses:* 3400; *Total Annual Hours:* 224,435 hours in year one and 166,435 hours in years two and three (For policy questions regarding the QHP Certification data collection, contact Lourdes Grindal-Miller at (301) 492-4345. For policy questions regarding risk adjustment and reinsurance data collection, contact Milan Shah call (301) 492-4427. For all other issues, call (410) 786-1326.)

2. *Type of Information Collection Request:* New collection; *Title of information collection:* Data Collection to Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program; *Use:* In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send 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.

Section 1311(b)(1)(B) of the Affordable Care Act requires that the Small Business Health Option Program (SHOP) assist qualified small employers in facilitating the enrollment of their employees in qualified health programs (QHPs) offered in the small group market. Section 1311(c)(1)(F) of the Affordable Care Act requires HHS to establish criteria for certification of health plans as QHPs and that these criteria must require plans to utilize a uniform enrollment form that qualified employers may use. Further, section 1311(c)(5)(B) requires HHS to develop a model application and Web site that assists employers in determining if they are eligible to participate in SHOP. Consistent with these authorities, HHS has developed a single, streamlined form that employees will use apply to the SHOP. Section 155.730 of the Exchanges Final Rule (77 FR 18310) provides more detail about this "single employee application," which will be used to determine employee eligibility, QHP selection, and enrollment of qualified employees and their dependents.

The information will be required of each employee upon initial application with subsequent information collections for the purposes of confirming accuracy of previous submissions or updating information from previous submissions. Information collection will begin during initial open enrollment in October 2013, per § 155.410 of the Exchanges Final Rule. Applications for the SHOP will be collected year round, per the rolling enrollment requirements of § 155.725 of the Exchanges Final Rule.

Employees will be able to submit an application for the SHOP online, using a paper application, over the phone through a call center operated by an Exchange, or in person through an agent, broker, or Navigator, per § 155.730(f) of the Exchanges Final Rule. If an employee does not enroll in coverage through the SHOP, the information will be erased after a specified period of time. If an employee enrolls in coverage through the SHOP, the information will be retained to document the enrollment, to allow reconciliation with issuer records, and to provide information for future coverage renewals or changes in coverage.

Every qualified employee of an employer participating in the SHOP who wishes to apply for coverage through the SHOP will need to complete an application to determine his or her eligibility, QHP selection, and enrollment of the employee and his or her dependents. The applicant will also be asked to verify his or her

understanding of the application and sign attestations regarding information in the application. The completed application will be submitted to the SHOP in the employer's state.

Applicants who choose to complete the electronic application will need to create an online account at the beginning of the application process.

We estimate that it will take approximately 0.159 hours (9.53 minutes) per applicant to submit a completed paper application. The Congressional Budget Office (CBO) estimates approximately 3 million people will enroll in health insurance through a SHOP in 2014. Assuming family size of approximately 3 per employee, we expect approximately 1 million employees to complete an application in 2014 for a total of approximately 93,300 burden hours.

CBO estimates approximately 2 million people will enroll in health insurance through a SHOP in 2015 and 3 million in 2016. Consequently, we estimate that approximately 666,666 employees will apply to a SHOP in 2015 and approximately 1 million will apply in 2016. *Form Number:* CMS-10438 (OCN: 0938-NEW); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 1,000,000; *Total Annual Responses:* 1,000,000; *Total Annual Hours:* 93,300 hours. (For policy questions regarding this collection contact Leigha Basini at 301-492-4307. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* New collection; *Title of information collection:* Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in the Small Business Health Options Program; *Use:* In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send 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.

Section 1311(b)(1)(B) of the Affordable Care Act requires that the SHOP assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Section 1311(c)(1)(F) of the Affordable Care Act requires HHS to establish criteria for certification of health plans as QHPs and that these criteria must require plans to utilize a uniform enrollment form that qualified employers may use. Further, section 1311(c)(5)(B) requires HHS to develop a model application and Web site that assists employers in determining if they are eligible to participate in SHOP. Consistent with these authorities, HHS has developed a single, streamlined form that employers will use to apply to the SHOP. Section 155.730 of the Exchanges Final Rule (77 FR 18310) provides more detail about this "single employer application," which will be used to determine employer eligibility and to collect information necessary for purchasing coverage through the SHOP.

The information will be required of each employer upon initial application with subsequent information collections for the purposes of confirming accuracy of previous submissions or updating information from previous submissions. Information collection will begin during initial open enrollment in October 2013, per § 155.410 of the Exchanges Final Rule. Applications for the SHOP will be collected year round, per the rolling enrollment requirements of § 155.725 of the Exchanges Final Rule.

Employers will be able to submit an application for the SHOP online, using a paper application, over the phone through a call center operated by an Exchange, or in person through an agent, broker, or Navigator, per § 155.730(f) of the Exchanges Final Rule. If an employer does not complete the application, the information will be erased after a specified period of time. If an employer completes the application and offers coverage to qualified employees through the SHOP, the information will be retained to document the offer of coverage, to allow reconciliation with issuer records, and to provide information for future coverage renewals or changes in coverage.

Every employer wishing to apply for coverage through the SHOP will need to complete an application to determine its eligibility to participate in the SHOP and to provide the information necessary for the employer to purchase coverage through the SHOP. The applicant will also be asked to verify his or her understanding of the application

and sign attestations regarding information in the application. The completed application will be submitted to the SHOP in the employer's state. Applicants who choose to complete the electronic application will need to create an online account at the beginning of the application process.

We estimate that it will take approximately 0.209 hours (12.57 minutes) per applicant to submit a completed paper application. We had several individuals fill out the paper application, averaged their times to complete the application, and factored in additional time due to potential variation in applicants' health literacy rate. The Congressional Budget Office (CBO) estimates approximately 3 million people will enroll in health insurance through a SHOP in 2014. Assuming a small business size of approximately 5 employees and a family size of approximately 3 per employee, we estimate that approximately 200,000 employers will apply to a SHOP in 2014. Consequently, we expect approximately 200,000 employers to complete an application in 2014 for a total of approximately 24,520 burden hours.

CBO estimates approximately 2 million people will enroll in health insurance through a SHOP in 2015 and 3 million in 2016. Consequently, we estimate that approximately 133,333 employers will apply to a SHOP in 2015 and approximately 200,000 will apply in 2016. *Form Number:* CMS-10439 (OCN: 0938-NEW); *Frequency:* Once per year; *Affected Public:* Private Sector: Business or other for-profit, non-for-profit institutions, or farms; *Number of Respondents:* 200,000; *Total Annual Responses:* 200,000; *Total Annual Hours:* 24,520 hours. (For policy questions regarding this collection contact Leigha Basini at 301-492-4307. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request:* New collection; *Title of information collection:* Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Affordable Insurance Exchanges, Medicaid and Children's Health Insurance Program Agencies; *Use:* In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send 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.

Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each State a single, streamlined form that may be used to apply for coverage through the Exchange and Insurance Affordability Programs, including Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program, as applicable. The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who qualify for the programs. A State may develop and use its own single streamlined application if approved by the Secretary in accordance with section 1413 and if it meets the standards established by the Secretary.

Section 155.405(a) of the Exchange Final Rule (77 FR 18310) provides more detail about the application that must be used by the Exchange to determine eligibility and to collect information necessary for enrollment. The regulations in § 435.907 and § 457.330 establish the requirements for State Medicaid and CHIP agencies related to the use of the single streamlined application. CMS is designing the single streamlined application to be a dynamic online application that will tailor the amount of data required from an applicant based on the applicant's circumstances and responses to particular questions. The paper version of the application will not be able to be tailored in the same way but is being designed to collect only the data required to determine eligibility. Individuals will be able to submit an application online, through the mail, over the phone through a call center, or in person, per § 155.405(c)(2) of the Exchange Final Rule, as well as through other commonly available electronic means as noted in § 435.907(a) and § 457.330 of the Medicaid Final Rule. The application may be submitted to an Exchange, Medicaid or CHIP agency.

The online application process will vary depending on each applicant's circumstances, their experience with health insurance applications and

online capabilities. The goal is to solicit sufficient information so that in most cases no further inquiry will be needed. We estimate that on average it will take approximately .50 hours (30 minutes) to complete for people applying for Insurance Affordability Programs. It will take an estimated .25 hours (15 minutes) to complete without consideration for Insurance Affordability Programs. We expect approximately 7,700,260 applications to be submitted for Insurance Affordability Programs between 2014 and 2016. The total burden is estimated to be 2,264,329 hours for 2014, and 605,920 hours and 979,881 hours for years 2015 and 2016, respectively. We estimate 1,139,240 applications to be submitted online without consideration for Insurance Affordability Programs between 2014 and 2016, resulting in 71,203 hours of burden each year in 2014 and in 2015, and 142,405 burden hours in 2016. The paper application process will take approximately .75 hours (45 minutes) to complete for those applying for Insurance Affordability Programs and .33 hours (20 minutes) for those applying without consideration for Insurance Affordability Programs. We expect approximately 855,584 applications to be submitted for Insurance Affordability Programs on paper in 2014 through 2016 for a total of 377,388 estimated burden hours in 2014. The burden hours are projected to be 100,987 hours and 163,314 hours in 2015 and 2016, respectively. We estimate 126,581 applications will be submitted without consideration for Insurance Affordability Programs from 2014 through 2016. Total burden hours are expected to be 10,443 hours in 2014 and 2015, and 20,886, in 2016. *Form Number:* CMS-10440 (OCN: 0938-NEW); *Frequency:* Once per year; *Affected Public:* Individuals and households; *Number of Respondents:* 3,273,889; *Total Annual Responses:* 3,273,889; *Total Annual Hours:* 1,669,683 hours. (For policy questions regarding this collection contact Hannah Moore at 301-492-4232. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' 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 4, 2012*:

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 (____), Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 29, 2012.

Martique Jones,

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

[FR Doc. 2012-16508 Filed 7-2-12; 11:15 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10427 and CMS-10437]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send 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 function; (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.