DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting Notice for the President’s Advisory Council on Faith-Based and Neighborhood Partnerships

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the President’s Advisory Council on Faith-based and Neighborhood Partnerships announces the following three conference calls:

Name: President’s Advisory Council on Faith-based and Neighborhood Partnerships

Time and Date: Wednesday, February 13th, 4:00 p.m.–5:30 p.m. (e.s.t.); February 27th, 4:00 p.m.–5:30 p.m. (e.s.t.); Wednesday, March 13th, 4:00 p.m.–5:30 p.m. (e.s.t.)

Place: All meetings announced herein will be held by conference call. The call-in line is: 1–866–823–5144. Passcode: 1375705. Space is limited so please RSVP to partnerships@hhs.gov to participate.

Status: Open to the public, limited only by lines available.

Purpose: The Council brings together leaders and experts in fields related to the work of faith-based and neighborhood organizations in order to: Identify best practices and successful modes of delivering social services; evaluate the need for improvements in the implementation and coordination of public policies relating to faith-based and other neighborhood organizations; and make recommendations for changes in policies, programs, and practices.

Contact Person for Additional Information: Please contact Ben O’Dell for any additional information about the President’s Advisory Council meeting at partnerships@hhs.gov.

Agenda: Please visit http://www.whitehouse.gov/partnerships for further updates on the Agenda for the meeting.

Public Comment: There will be an opportunity for public comment at the conclusion of the meeting. Comments and questions can be asked over the conference call line, or sent in advance to partnerships@hhs.gov.


Ben O’Dell,
Associate Director for Center for Faith-based and Neighborhood Partnerships at U.S. Department of Health and Human Services.

BILLING CODE 4154–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10438, CMS–10439 and CMS–10440]

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.

1. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Data Collection to Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program; Use: 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 eligibility.

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. 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.

The 60-day Federal Register notice published on July 6, 2012 (77 FR 40061). We received public comments from over 20 entities addressing topics such as the purpose and use of the information collection and burden estimates. Some of the commenters were concerned with duplicate or overly burdensome data collection as related to the employee application. CMS is working with states to minimize any required document submission to streamline and reduce duplication, especially in future years. We have taken into consideration all of the proposed suggestions and have made changes to this collection of information, such as adding a privacy statement, information on the availability of other coverage, pre-population of certain applicant information, and whether the employee is waiving SHOP coverage.

**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.)

2. Type of Information Collection Request: New collection (Request for a new OMB control number); **Title of Information Collection:** Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in the Small Business Health Options Program; **Use:** 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 apply to the SHOP. Section 155.730 of the Exchanges Final Rule provides more detail about this “single employer application,” which will be used to determine employer eligibility.

This 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. 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 1, 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.

The 60-day Federal Register notice published on July 6, 2012 (77 FR 40061). We received public comments from over 20 entities addressing topics such as the purpose and use of the information collection and burden estimates. Some of the commenters were concerned with duplicate or overly burdensome data collection as related to the employer application. CMS is working with States to minimize any required document submission to streamline and reduce duplication, especially in future years. We have taken into consideration all of the proposed suggestions and have made changes to this collection of information, such as adding a privacy statement, “doing business as” information, employer type, and making electronic notices the default option. Some information related to the employer choice of plan offerings and contribution is removed because it is not necessary for an eligibility determination.

**Form Number:** CMS–10439 (OCN: 0938–NEW); **Frequency:** Annually; **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.)

3. Type of Information Collection Request: New collection (Request for a new OMB control number); **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:** 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

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1 Based on US Census data of business size in 2008, the vast majority of employer firms (restricted to employer firms with 1–99 employees) have 1–4 employees. Based on ASPE analysis of 2011 Current Population Survey data, the average family size (restricted to individuals under the age of 65) with income above 400% Federal Poverty Level is 3.16
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. It is expected approximately 7,840,477 applications to be submitted for Insurance Affordability Programs during 2014 and 2016. The total burden is estimated to be 5,548,859 cumulative burden hours. We estimate 1,263,823 applications to be submitted online without consideration for Insurance Affordability Programs between 2014 and 2016, resulting in 284,281 cumulative burden hours. The paper application 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 784,048 applications to be submitted for Insurance Affordability Programs on paper in 2014 through 2016 for a cumulative total of 588,035 burden hours. We estimate 126,583 applications will be submitted without consideration for Insurance Affordability Programs from 2014 through 2016. Total burden hours are expected to be 41,772 burden between 2014 and 2016. CMS received approximately 65 public comments in response to the 60 day notice. These comments addressed a range of topics, including the application process, paper and/or online accessibility, processes for verifying information, privacy and security of information, and the types of questions or data elements that should be included. CMS made significant changes to the application materials, namely moving from categories of data elements to completed draft applications. Because of the significant changes throughout, it is not feasible to list each individual change. CMS also adjusted the burden estimates due to changes in coverage estimates due to Congressional Budget Office revisions from July 2012. The expected number of applications between 2014–2016 has increased to 7,840,477 from 7,700,260; the estimated burden hours have increased from 5,548,859 to 1,812,230. Form Number: CMS–10440 (OCN: 0938–NEW); Frequency: Once per year; Affected Public: Individuals and Households; Number of Respondents: 3,035,434; Total Annual Responses: 3,035,434; Total Annual Hours: 1,085,944 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.

To be assured consideration, comments and recommendations for the proposed information collections must be received at OMB’s desk officer at the address below, no later than 5 p.m. on February 28, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: OIRA_submission@omb.eop.gov.

Dated: January 22, 2013.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0012]

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA), Office of Foods has modified its structure and reorganized to the Office of Foods and Veterinary Medicine (OFVM). This new organizational structure was approved by the Secretary of Health and Human Services on July 20, 2012, and implemented on October 1, 2012.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4500.

SUPPLEMENTARY INFORMATION:

I. Summary

Part D, Chapter D–B (Food and Drug Administration), Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56605, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 74 FR 41713, August 18, 2009; and 76 FR 45270, July 28, 2011) is amended in recognition of the fact that most of the work of the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine affects the food system as a whole and requires an integrated approach, FDA has modified the Office of Foods structure and reorganized to the OFVM. This reorganization will allow for effective implementation of the new, risk-based mandates of the FDA Food Safety Modernization Act (Pub. L. 111–353) and the demand the law places on FDA for an integrated implementation