

Dated: September 8, 2011.

Martique Jones,

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

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Medicare & Medicaid
Services**

[Document Identifier: CMS-10334]

**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:* Revision of a currently approved collection; *Title of Information Collection:* Application for Coverage in the Pre-Existing Condition Insurance Plan; *Use:* The Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight is requesting clearance by the Office of Management and Budget for modifications to this previously approved collection package. These changes are being requested to (1) provide a mechanism for a PCIP enrollee who has moved from a state-administered PCIP to quickly and efficiently enroll into the federally-administered PCIP (2) provide a mechanism for a PCIP applicant to identify a third party entity will pay their premium to ensure appropriate

premium billing (3) provide a mechanism whereby a licensed insurance agent or broker may identify their referral of an applicant (4) request employer information to expand ways to identify and prevent instances of insurer dumping and (5) make clarifications to existing application language. *Form Number:* CMS-10334 (OCN: 0938-1095) *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 83,333; *Number of Responses:* 83,333; *Total Annual Hours:* 179,499. (For policy questions regarding this collection, contact Laura Dash at 410-786-8623. 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 E-mail 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 by the OMB desk officer at the address below, no later than 5 p.m. on *October 14, 2011*

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

Dated: September 8, 2011.

Martique Jones,

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

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Medicare & Medicaid
Services**

[CMS-9980-NC]

**Request for Information Regarding
State Flexibility To Establish a Basic
Health Program Under the Affordable
Care Act**

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

ACTION: Request for information.

SUMMARY: This notice is a request for information regarding section 1331 of the Affordable Care Act, which provides States with the option to establish a Basic Health Program. This option

permits States to enter into contracts to offer one or more "standard health plans" providing at least the essential health benefits described in section 1302(b) of the Affordable Care Act to eligible individuals in lieu of offering such individuals coverage through the Affordable Insurance Exchange (Exchange).

DATES: *Comment Date:* To be assured consideration, responses must be received at one of the addresses provided below, no later than 5 p.m. on October 31, 2011.

ADDRESSES: In responding, please refer to file code CMS-9980-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit responses in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-9980-NC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-9980-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Shaina Rood, (301) 492–4422.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Section 1331(a) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), referred to collectively as the Affordable Care Act, directs the Secretary of Health and Human Services (the Secretary) to establish a Basic Health Program under which States may enter into contracts with one or more standard health plans that provide health coverage to eligible individuals in lieu of offering such individuals coverage through the Exchange. For States choosing this option, section 1331(a)(2) of the Affordable Care Act provides that the Secretary certify that the amount of the monthly premium

charged to eligible individuals enrolled in a plan under contract under this program, called a standard health plan, does not exceed the amount of the monthly premium that an eligible individual would have paid if he or she were to receive coverage from the applicable benchmark plans (as defined in section 36B(b)(3)(B) of the Internal Revenue Code of 1986) through the Exchange. This section also directs the Secretary to certify that cost-sharing does not exceed the standards specified in section 1331(a)(2)(A)(ii) of the Affordable Care Act.

Section 1331(b) of the Affordable Care Act defines a standard health plan as one selected by the State that: (1) Only enrolls applicants who are determined eligible using the eligibility standards specified in section 1331(e) of the Affordable Care Act; (2) covers at least the essential health benefits described in section 1302(b) of the Affordable Care Act; and (3) in the case of a plan that provides health insurance coverage offered by a health insurance issuer, has a medical loss ratio of at least 85 percent.

Section 1331(c) of the Affordable Care Act specifies that a Basic Health Program will establish a competitive process for entering into contracts with standard health plans, including negotiation of premiums, cost-sharing, and benefits in addition to the essential health benefits. The statute provides that the State include in its competitive process the inclusion of innovative features such as care coordination and care management for enrollees, incentives for the use of preventive services, and the establishment of relationships between providers and patients that maximize patient involvement in health care decision-making. The contracting process shall also take into consideration, and make suitable allowances for, the differences in the health care needs of enrollees and the differences in local availability of, and access to, health care providers.

Section 1331(c)(2) of the Affordable Care Act provides that the competitive process shall also include contracting with managed care systems, or with systems that offer as many of the attributes of managed care as are feasible in the local health care market. The competitive contracting process shall also include the establishment of specific performance measures and standards for issuers that focus on quality of care and improved health outcomes. Section 1331(c)(3) provides that a State shall, to the maximum extent feasible, seek to make multiple standard health plans available to ensure individuals have a choice of

such plans. It also provides that a State may negotiate a regional compact with other States to include coverage of eligible individuals in all such States in agreements with issuers of standard health plans.

Section 1331(c)(4) of the Affordable Care Act directs a State choosing to establish a Basic Health Program to coordinate the administration of a Basic Health Program with Medicaid, the Children's Health Insurance Program (CHIP), and other State-administered health programs.

Section 1331(d)(1) of the Affordable Care Act allows the Secretary to transfer Federal funds to a State that establishes a Basic Health Program in accordance with the standards of the program under section 1331(a). Section 1331(d)(2) of the Affordable Care Act directs that a State establish a trust fund for the deposit of the Federal funds it receives for its Basic Health Program, and specifies that the amounts in the trust may only be used to reduce the premiums and cost-sharing of, or to provide additional benefits for, eligible individuals enrolled in standard health plans within a Basic Health Program.

Section 1331(d)(3) of the Affordable Care Act specifies that a State that operates a Basic Health Program will receive 95 percent of the amount of premium tax credits, and the cost-sharing reductions, that would have been provided to (or on behalf of) eligible individuals enrolled in standard health plans through a Basic Health Program, if the eligible individuals were instead enrolled in qualified health plans (QHP) through the Exchange and receiving premium tax credits and cost-sharing reductions. To determine the amount of payment, the Secretary shall take into account all relevant factors necessary to determine the amount that would have been provided to eligible individuals as specified in 1331(d)(3), including, but not limited to, whether any reconciliation of the credit or cost-sharing reductions would have occurred if the enrollee had been so enrolled.

Section 1331(d)(3) also provides that the determination shall also take into consideration the experience of other States with respect to participation in an Exchange and such credits and reductions provided to residents of the other States, with a special focus on enrollees with income below 200 percent of poverty. Additionally, the Secretary shall adjust the amount of payment for any fiscal year to reflect any error in the determinations for any preceding fiscal year.

Section 1331(e) of the Affordable Care Act specifies eligibility standards for a Basic Health Program. To be determined

eligible for a Basic Health Program, an individual must:

- (1) Be a resident of a State participating in a Basic Health Program;
- (2) Be eligible for enrollment in a QHP through the Exchange but for the existence of a Basic Health Program;
- (3) Not be eligible to enroll in the State's Medicaid program under title XIX of the Social Security Act (the Act), for benefits that at a minimum consist of the essential health benefits described in section 1302(b) of the Act;
- (4) Have a household income that exceeds 133 percent but does not exceed 200 percent of the Federal poverty level (FPL), or, for a non-citizen lawfully present who is not eligible for Medicaid based on immigration status, a household income that is not greater than 133 percent of the FPL;
- (5) Not be eligible for minimum essential coverage or is eligible for an employer-sponsored plan that is not affordable coverage; and
- (6) Not have attained age 65 as of the beginning of the plan year.

Section 1331(f) of the Affordable Care Act directs the Secretary to conduct an annual review of each State Basic Health Program to ensure that it complies with the standards of section 1331. Through this annual review, the State will provide information to demonstrate that its Basic Health Program meets: (1) Eligibility verification standards for participation in the program; (2) standards for the use of Federal funds received by the program; and (3) quality and performance standards.

As specified in section 1331(g) of the Affordable Care Act, a standard health plan offeror may be a licensed health maintenance organization, a licensed health insurance insurer, or a network of health care providers established to offer services under the program; the statute provides authority for the State to determine eligibility to offer a standard health plan.

II. Request for Information

Section 1321(a)(2) of the Affordable Care Act directs the Secretary to consult with stakeholders to ensure balanced representation among interested parties in issuing regulations to implement programs pursuant to title I. The Department of Health and Human Services has consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners, regular contact with States through the Exchange grant process, and meetings with tribal representatives, health insurance issuers, trade groups, consumer advocates, employers, and

other interested parties. This consultation will continue throughout the development of guidance and regulations related to the Basic Health Program.

As such, we are requesting information to aid in the development of standards for the establishment and operation of a Basic Health Program. To assist in responding, this request for information describes the specific areas where input is particularly requested.

Specifically, we ask for responses to the questions below to provide the Secretary with relevant information for the development of guidance and regulations regarding the Basic Health Program. However, it is not necessary for respondents to address every question below and respondents may also address additional issues about the Basic Health Program that are not listed here. Individuals, groups, and organizations interested in providing responses may do so at their discretion by following the above mentioned instructions.

A. General Provisions

1. What are some of the major factors that States are likely to consider in determining whether to establish a Basic Health Program? Are there additional flexibilities, advantages, costs, savings or challenges for the State and/or consumer that would make this option more or less attractive to States? If so, what are they?

2. What are key considerations for States in placing responsibility for a Basic Health Program within the State organizational structure?

3. What are the challenges and costs associated with managing a Basic Health Program?

4. Are States that are exploring the Basic Health Program considering implementation for 2014, or for later years? What are the key tasks that need to be accomplished, and within what timeframes, to implement the Basic Health Program in a timely fashion? What kinds of business functions will need to be operational before implementation, and how soon will they need to be operational? Are there opportunities to leverage existing systems and increase efficiency within the State structure? To what extent have States begun developing business plans or budgets relating to Basic Health Program implementation?

5. To what extent have States already begun to assess whether to establish a Basic Health Program? What internal and/or external entities are involved, or will likely be involved in this planning process?

6. What guidance or information would be helpful to States, plans, and other stakeholders as they begin the planning process? What other terms or provisions need additional clarification to facilitate implementation and compliance? What specific clarifications would be helpful?

7. How can the Administration provide technical assistance? What form(s) of technical assistance would be most helpful to States?

B. Standard Health Plan Standards and Standard Health Plan Offerors

1. What additional standards, if any, should standard health plans participating in a State's Basic Health Program meet? What consumer protections should be included? How should quality and performance be measured?

2. What plan design issues should be considered? How likely is it for a State to consider an expanded benefit package beyond the essential health benefits for standard health plans participating in a State's Basic Health Program? What are the advantages and disadvantages of an expanded benefit package for standard health plans compared to qualified health plans?

3. What is the expected impact of standard health plans on provider payments and consumer access?

C. Contracting Process

1. What innovative features should States consider when negotiating through the contracting process with standard health plans to participate in a Basic Health Program?

2. What considerations exist in determining whether to utilize the regional compact authority in Section 1331(c)(3)(B) of the Affordable Care Act? Are States interested in pursuing this approach?

D. Coordination With Other State Programs

1. What is the expected impact of a Basic Health Program on the Exchange's purchasing power and viability? How might States organize a Basic Health Program with respect to purchasing structure?

2. What is the expected impact of a Basic Health Program on plans participating in the Exchange in terms of risk profile, enrollment, and premium stability? What is the expected impact on overall coverage?

3. What are some of the major factors that States are likely to consider in determining how to structure their Basic Health Program? Are States likely to structure the Basic Health Program as one component of its other public

programs? Are States likely to consider a CHIP-like approach or other options? What are the pros and cons of these various options?

4. How can eligibility and enrollment be effectively coordinated between the Basic Health Program and other State programs to reduce churning between programs and promote continuity of care?

5. How could establishing a Basic Health Program affect the ability of an entire family to be covered by the same plan?

6. Are standard health plans likely to also participate in other coverage programs, such as the Exchanges, Medicaid, or CHIP? Should this be encouraged, and if so, how could CMS and States encourage it?

E. Amount of Payment

1. The statute specifies that amounts in the trust fund may only be used to reduce the premiums and cost-sharing of, or to provide additional benefits for, eligible individuals enrolled in standard health plans within a Basic Health Program. What options are States considering for reducing premiums and cost-sharing, or providing additional benefits? What, if any, guidance is needed on this provision?

2. What are the likely administrative costs for a Basic Health Program? What factors, especially in terms of resources, are likely to affect a State's ability to establish a Basic Health Program? How are States likely to fund the costs associated with establishing and administering a Basic Health Program?

3. The statute specifies that in developing the financial methodology for the Basic Health Program, the determination of the value of the premium tax credits and cost-sharing reductions should take into consideration the experience of other States. What information would be most helpful to inform this methodology? Should implementation of the Basic Health Program be postponed until other States' experiences are available?

4. Other than those listed in the statute, what factors should be considered when establishing the methodology for determining the amount of Basic Health Program funding to States? How should the Federal government implement this calculation?

5. The statute specifies that the funding calculation is on a per-enrollee basis. How should the Federal government acquire the detailed information necessary to perform this calculation?

6. What are the best State-specific data sources to use in estimating the

availability of affordable employer-sponsored insurance?

7. What methods should be considered to measure and monitor compliance with the 95 percent cap on funding? How should CMS implement the provisions in Section 1331(d)(3)(B) of the Affordable Care Act regarding corrections to overpayments made in any year?

F. Eligibility

1. What education and outreach will be necessary to facilitate a helpful consumer experience?

G. Secretarial Oversight

1. What process should the Secretary use to certify or recertify Basic Health Programs? How should this process be similar to or different from Exchange certification?

2. What should be considered when developing an oversight process for the Basic Health Program?

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: July 27, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011-23388 Filed 9-9-11; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Food and Drug Administration/Xavier University Global Outsourcing Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University Global Outsourcing Conference." This 2.5-day public conference for the pharmaceutical industry is in direct alignment with the "FDA Strategic Priorities 2011-2015," and includes presentations from key FDA officials, global regulators, and industry experts. This conference drives collaboration on the topic of global outsourcing compliance by bringing pharmaceutical/biotechnology companies and contract partners to the

same event to address the issues that reside on both sides of the contract. Expert presentations address the "how to" aspects of improving outsourced product quality through topics such as Strategic Procurement, End-to-End lifecycle product management, Managing Global Complex Supply Chains, and other topics. The experience level of our audience has fostered engaged dialog that has lead to innovative initiatives.

Dates and Times: The public conference will be held on October 3, 2011, from 8:30 a.m. to 5 p.m., October 4, 2011, from 8:30 a.m. to 5 p.m., and October 5, 2011, from 8:30 a.m. to 1 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

Contact Persons:

For information regarding this document: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East Seventh Street, Cincinnati, OH 45202, 513-246-4134, e-mail: steven.eastham@fda.hhs.gov.

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, e-mail: phillipsm4@xavier.edu.

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, dinners, and dinner speakers for the 2.5 days of the conference. Prior online registration or registration by mail must be done by October 3, 2011. There will also be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES¹

Attendee	Fee
Industry	\$1,495
Small Business (<100 employees)	1,000
Consultants	700
Startup Manufacturer	300
Academic/Government	300
Media	Free

¹ The fourth registration from the same company is free.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the "Register Now" link on the conference Web site at <http://www.XavierGOC.com>. FDA has verified the Web site address, but is not responsible for subsequent changes to