Coverage of Certain Preventive Services Under the Affordable Care Act
REG 120391-10
February 2012

SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSIONS

1. *Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.*

The Patient Protection and Affordable Care Act, Public Law 111-148, (the Affordable Care Act) was enacted by President Obama on March 23, 2010 and amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 on March 30, 2010. As part of the Act, Congress added section 2713 to the Public Health Service (PHS) Act. The Departments of Health and Human Services, Labor, and Treasury (the Departments) published interim final rules (2010 interim final rules) on July 19, 2010 to require non-grandfathered group health insurance coverage to provide benefits for certain preventive services without cost sharing. On August 1, 2011, Health Resources and Services Administration (HRSA), one of the entities providing lists of covered preventive services, adopted and released guidelines providing for the coverage of contraceptive services. On August 3, 2011, the Departments amended the 2010 interim final rules (2011 amended interim final rules) to provide HRSA with the authority to exempt group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) from the requirement to cover contraceptive services provided in the guidelines and to specify what a religious employer is for the exemption. HRSA exercised its authority in its guidelines to exempt religious employers from the requirement to cover contraceptive services.

On February 10, 2012, the Departments issued final rules that adopted the definition of religious employer in the 2011 amended interim final rules for purposes of the exemption to cover contraceptive services. The Departments also issued guidance establishing a one year enforcement safe harbor for group health plans established or maintained by certain nonprofit organizations that have religious objections to contraceptive coverage (and any group health insurance provided in connection with such plans). The safe harbor is in effect until the first plan year that begins on or after August 1, 2013.

The proposed rules would establish accommodations for contraceptive coverage for health coverage established or maintained by eligible organizations with religious objections to contraceptive services. The proposed rules would require each eligible organization to self-certify that it meets the definition of an eligible organization. An eligible organization can utilize a model form provided on the Internet to prepare the self-certification. The eligible organization would provide its health insurance issuer or third party administrator with a copy of its self-certification.

2. *Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.*

This is a third-party reporting requirement. Health insurance issuers would utilize this information to provide written notice to participants and beneficiaries in insured plans of eligible organizations concerning how individual contraceptive coverage will be provided. The issuers would provide the same notice to participants and beneficiaries in self-insured plans of eligible organizations whose coverage is arranged for them by a third party administrator. The government would review the notices only upon examinations conducted to ensure that participants and beneficiaries of eligible organizations are receiving notice of their rights.

3. *Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration for using information technology to reduce burden.*

The proposed regulations do not limit the ability of affected plans to furnish information required by the regulation to issuers or third party administrators via electronic media.

4. *Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above*.

The proposed information collection does not require duplicative information.

5. *If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.*

The plan only has to self-certify one time. The plan maintains the self-certification in its own records and is not required to submit it to the government. The plan only has to send this self-certification to its issuer or third-party administrator, and can do so electronically to further reduce burden.

6. *Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden*.

The Department only requires a one-time self-certification. If this self-certification does not occur, the Department cannot verify that an organization has qualified for an accommodation, while avoiding any inquiry into the organization's character, mission, or practices. Also without the notice issuers and third-party administrators will not know to provide a separate health insurance policy for contraceptive coverage to the plans participants and beneficiaries

7. *Explain any special circumstances that would cause an information collection to be conducted in a manner:*

- *requiring respondents to report information to the agency more often than quarterly;*
- *requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;*
- *requiring respondents to submit more than an original and two copies of any document;*
- *requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;*
- *in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;*
- *requiring the use of a statistical data classification that has not been reviewed and approved by OMB;*
- *that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or*
- *requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.*

None.

8. *If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.*

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and record keeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The notice of proposed rulemaking allows for 60-days to comment. The notice was published February 6, 2013 at 78 FR 8833.

9. *Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.*

Not applicable.

10. *Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.*

Not applicable.

11. *Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.*

No additional justifications beyond those included in Question 1.

12. *Provide estimates of the hour burden of the collection of information. The statement should:*

- *Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.*

- *If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.*

- *Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 13.*

Each organization seeking accommodation under the proposed rules would be required to self-certify that it meets the definition of an eligible organization. The self-certification would be executed by an authorized representative of the organization and would also specify the contraceptive services for which the organization will not administer or fund coverage. The self-certification would not be submitted to the Departments. The form that would be used by organizations for their self-certification would be specified. This

form is available for inspection at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html. The organization would maintain the self-certification in its records for each plan year to which the accommodation is to apply. The eligible organization would need to provide a copy of its self-certification to a health insurance issuer (for insured group health plans or student health insurance coverage) or to a third party administrator (for self-insured group health plans). As the notice can be sent electronically the burden is de minimis.

As noted in the proposed rule, the Department does not have an estimate for how many organizations would seek an accommodation. The Department seeks comment on the likely number of organizations seeking an accommodation and the number of participants and beneficiaries in the plans of such organizations. It is assumed that, for each eligible organization, clerical staff would gather and enter the necessary information and send the self-certification electronically to the issuer or third party administrator, a manager and legal counsel would review it, and a senior executive would execute it. The Department estimates that an organization would need approximately 50 minutes (30 minutes of clerical labor at a cost of $30.64 per hour, 10 minutes for a manager at a cost of $55.22 per hour, 5 minutes for legal counsel at a cost of $83.10 per hour, and 5 minutes for a senior executive at a cost of $112.43 per hour) to execute the self-certification. Therefore, the total annual burden for preparing and providing the information in the self-certification would be approximately 50 minutes for each eligible organization with an equivalent cost burden of $41.

13. *Provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12.)*

None

14. *Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.*

None

15. *Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.*

New information collection requirements.

16. *For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.*

Not applicable.

17. *If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.*

Not applicable.

18. *Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB 83-I.*

Not applicable; no exceptions to the certification statement.