

**Coverage of Certain Preventive Services Under the Affordable Care Act—For-Profit
Entities**
OMB Control Number 1210-0NEW
August 2014

NOTE

This Information Collection Request (ICR) is being submitted for the purpose of having the OMB review the information collection requirements identified in a Notice of Proposed Rulemaking published in the Federal Register on August 27, 2014 (79 FR 51118). The Department anticipates public comment and requests OMB to file comment with an instruction to consider public comments submitted in response to the NPRM in preparing an ICR for the final rule to be submitted under control number 1210-0150.

For transparency purposes, this supporting statement also discusses the information collection requirements contain in a related Interim Final Rule concurrently published in the *Federal Register* (79 FR 51092). On August 27, 2014, the OMB approved those requirements through February 28, 2015, under control number 1210-0150. See ICR Reference Number [121408-1210-005](#).

SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSION

Part A. Justification.

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. The Affordable Care Act added section 2713 to the Public Health Service (PHS) Act and incorporated this provision into the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code (Code). 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, including benefits for certain women's preventive health services as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

On August 1, 2011, HRSA adopted and released guidelines for women's preventive health services, including 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

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insurance coverage provided in connection with such plans) from the requirement to cover contraceptive services consistent with the HRSA guidelines. The 2011 amended interim final rules specified a definition of religious employer. HRSA exercised its authority in its guidelines to exempt 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.

On February 10, 2012, the Departments issued final rules that adopted the definition of religious employer in the 2011 amended interim final rules without modification (2012 final regulations) and issued guidance establishing a one year enforcement safe harbor for group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and group health insurance provided in connection with such plans). The guidance provided that the temporary enforcement safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. On March 21, 2012, the Departments published an advance notice of proposed rulemaking that described and solicited comments on possible approaches to achieve the goals of providing coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously protecting certain additional nonprofit organizations with religious objections to contraceptive coverage from having to contract, arrange, pay, or refer for such coverage.

On February 6, 2013, the Departments published proposed rules that proposed to simplify and clarify the definition of religious employer and also proposed accommodations for health coverage established or maintained or arranged by certain nonprofit religious organizations with religious objections to contraceptive services (eligible organizations). The rules proposed that, for insured plans, the health insurance issuer providing group health insurance coverage in connection with the plan would be required to assume sole responsibility, independent of the eligible organization and its plan, for providing contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. In the case of self-insured plans, the proposed regulations presented potential approaches under which the third party administrator of the plan would provide or arrange for a third party to provide separate contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. The Departments received over 400,000 comments (many of them standardized form letters) in response to the proposed regulations.

After consideration of the comments, the Departments published final regulations on July 2, 2013. A contemporaneously-issued HHS guidance document extended the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This

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guidance included a form to be used by an organization during this temporary period to self-certify that its plan qualifies for the temporary enforcement safe harbor. In addition, HHS and the Department of Labor also issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under these final regulations. This self-certification form was provided for use with the accommodations under the July 2013 final regulations, after the expiration of the temporary enforcement safe harbor (that is, for plan years beginning on or after January 1, 2014). The rules also provide that the third party administrator and issuer that is required to provide or arrange payments for contraceptive services must provide plan participants and beneficiaries with written notice of the availability of separate payments for contraceptive services contemporaneous with, but separate from, any application materials distributed in connection with enrollment for group health coverage for each plan year to which the accommodation is to apply. The EBSA Form 700 and the notice to HHS are information collection requests (ICRs) subject to the Paperwork Reduction Act.

2014 IFR Revision

On July 3, 2014, the Supreme Court of the United States issued an interim order in connection with an application for an injunction in the pending case of Wheaton College v. Burwell, ruling that, “[i]f [Wheaton College] informs the Secretary of Health and Human Services in writing that it is a non-profit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing against [Wheaton College]” certain provisions of the Affordable Care Act and related regulations requiring coverage without cost-sharing of certain contraceptive services “pending final disposition of appellate review” (Wheaton order). The order stated that Wheaton College need not use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for this injunctive relief. The order also stated that it neither affected “the ability of [Wheaton College’s] employees and students to obtain, without cost, the full range of FDA approved contraceptives,” nor precluded the Government from relying on the notice it receives from Wheaton College “to facilitate the provision of full contraceptive coverage under the Act.”

The Departments are issuing the interim final regulations in light of the Supreme Court’s interim order concerning notification to the Federal government that an eligible organization has a religious objection to providing contraceptive coverage, as an alternative to the EBSA Form 700, and to preserve participants’ and beneficiaries’ access to coverage for the full range of FDA-approved contraceptives, as prescribed by a health care provider, without cost sharing, which is also consistent with the Supreme Court’s order.

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The interim final regulations amend the EBSA Form 700 ICR. The Department is revising this ICR pursuant to the emergency PRA clearance procedures set forth under 5 CFR 1320.13 in order to implement the Supreme Court's order and make an alternative process for eligible organizations available as soon as possible. The use of normal Paperwork Reduction Act clearance procedures would delay implementation of the Court's order and the ability of eligible organizations to avail themselves of this alternative process.

2014 NPRM Revision

On June 30, 2014, the Supreme Court ruled in the case of Burwell v. Hobby Lobby Stores, Inc. that, under the Religious Freedom Restoration Act of 1993, the group health plan of three family-owned, closely held, for-profit corporations is exempt from the requirement to provide contraceptive coverage if the owners have religious objections to such coverage, because the Government's desired goal of guaranteeing access to coverage of contraceptive services without cost sharing could be achieved in a less restrictive manner, such as by offering such closely held, for-profit entities that have religious objections to contraceptive coverage the accommodation that the Government already provided to non-profit religious organizations with such religious objections.¹ The Court described this accommodation, and went on to state: "At minimum, however, [the accommodation] does not impinge on the plaintiffs' religious belief that providing insurance coverage for the contraceptives at issue here violates their religion, and it serves HHS' stated interests equally well."

The Departments are issuing this notice of proposed rulemaking to propose and invites comments on changes to the definition of an eligible organization in the Departments' regulations in light of the Supreme Court's decision in Hobby Lobby and any other steps the Government should take, if Congress fails to act expeditiously to ensure that employees in group health plans obtain, without cost, the full range of FDA approved contraceptives without cost sharing if enrolled in a plan sponsored or arranged by a closely held for-profit entity that objects on religious grounds to covering contraceptive services. Legislation would be the most timely and direct way to provide contraceptive coverage to people who lost it due to the Supreme Court decision. That said, given the importance of this coverage, initiating this proposed rulemaking now allows for public input and a pathway toward providing contraceptive coverage in the absence of a legislative solution.

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.*

¹ Burwell vs. Hobby Lobby Stores, Inc., 2014 WL 2921709, 573 U.S.---- (2014)

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The requirement to provide a self-certification or notice to HHS is a third-party reporting disclosure. These disclosures are required to exempt eligible organizations from contracting, arranging, paying, or referring for contraceptive coverage. Eligible organizations seeking the accommodation must maintain the self-certification or notice to HHS in a manner consistent with the record retention requirements under section 107 of the Employee Retirement Income Security Act of 1974, which generally requires records to be maintained for six years.

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 interim final regulations do not limit the ability of affected eligible organizations to furnish the self-certification or notice to HHS 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 information collection does not require duplicative information.

5. *If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.*

The eligible organization only has to complete the self-certification or notice to HHS one time, unless there is a change in its qualifications as an eligible organization, religious objection, health insurance issuer, or third party administrator.

If completing the EBSA Form 700, the eligible organization may maintain the self-certification in its own records after it is provided to issuers or third party administrators (as outlined in the regulations), and is not required to submit it to the government. If providing notice to HHS, the eligible organization may maintain the notice in its own records after it is provided to the government. The eligible organization may provide the self-certification electronically to further reduce burden.

For eligible organizations that provide notice to HHS, the Departments are providing model language that can be used to satisfy the notice requirement to minimize burden.

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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.*

If the self-certification or notice to HHS does not occur, there is no way to verify that an eligible organization is seeking an accommodation and there is no way to ensure that issuers or third party administrators will provide benefits for contraceptive services to 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.*

The regulations require the self-certification or notice to HHS to be maintained in a manner consistent with the record retention requirements under section 107 of the Employee Retirement Income Security Act of 1974, which generally requires records to be kept for six years.

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*

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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 Department published a NPRM in the *Federal Register* proposing changes to the definition of an eligible organization regulations in light of the Supreme Court's decision in the case of Burwell v. Hobby Lobby Stores, Inc., on August 27, 2014 (79 FR 51118). The NPRM invited comments on the information collections to be submitted to OMB. The NPRM also asked for public comments during a 60-day period on all aspects of the rule, including a specific request for matters of particular interest related to the PRA. The DOL anticipates public comment and asks the OMB to file comment on this information collection request.

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.*

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No additional justifications beyond those included in Item 1. An eligible organization seeking to take advantage of the accommodation would need to provide the self-certification or notice to HHS. The Department believes eligible organizations, themselves, would normally make such representations public under other circumstances. The regulations also require the self-certification or notice to HHS to be maintained in a manner consistent with the record retention requirements under section 107 of the Employee Retirement Income Security Act of 1974, which generally requires records to be kept for six years.

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.*
- *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.*

IFR

Each organization seeking to be treated as an eligible organization under the interim final rules must provide a self-certification to each third party administrator or issuer, or notice to HHS, of its religious objection to coverage of all or a subset of contraceptive services. The interim final regulations continue to allow such eligible organizations to notify an issuer or third party administrator using EBSA Form 700, as set forth in the July 2013 final regulations. In addition, the interim final regulations permit an alternative process, consistent with the Supreme Court's interim order in Wheaton College, under which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. The eligible organization must maintain the self-certification or notice to HHS in its records.

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The Department does not know the total number of organizations that would seek an accommodation. The Department sought comment on the likely number of organizations seeking an accommodation and the number of participants and beneficiaries in the plans of such organizations when the proposed regulations were issued in 2013, but received no comments. The Department knows, based on litigation, that approximately 122 eligible organizations would now have the option to provide the alternative notice to HHS rather than their third party administrators or issuers.

Therefore, the Department assumes that 122 eligible organizations will seek accommodation under the interim final regulations. In order to complete this task, the Department assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification electronically to the issuer or third party administrator as appropriate, or send the notice to HHS electronically.² The Department assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. The Department estimates that an eligible organization would spend approximately 45 minutes (30 minutes of clerical labor at a cost of \$30 per hour, 10 minutes for a compensation and benefits manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127, and 5 minutes by a senior executive at a cost of \$121) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$53 for a total hour burden of 102 hours with an equivalent cost of \$6,430

As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the hour burden so each will account for 51 burden hours.

NPRM

The NPRM would expand the definition of eligible organization to include certain for-profit organizations. The Department does not know how many organizations that would seek an accommodation. The Department knows, based on litigation, that approximately 71 eligible for-profit organizations would now have the option to seek accommodation.

Therefore, the Department assumes that 71 eligible organizations will seek accommodation under the proposed regulations. Using identical assumptions to the burden for the IFR it is estimated that there will be an hour burden of \$53 for each of the 71 eligible organizations for a total hour burden of 59 hours with an equivalent cost of \$1,870.

² For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

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As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the hour burden so each will account for 30 burden hours.

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.)*

IFR

The Department estimates that each self-certification or notice to HHS will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be \$0.54.

For purposes of this analysis, the Department assumes that all self-certifications or notices to HHS will be mailed. The total cost burden for the self-certifications or notices to HHS is approximately \$66.

As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the cost burden so each will account for \$33 of the cost burden.

NPRM

Using the same assumptions as those used for the IFR the total cost burden for the 71 organizations is \$38.

As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the cost burden so each will account for \$19 of the cost burden.

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*

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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 12 or 14.*

This is a new information collection being established through rulemaking.

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."*

Not applicable; no exceptions to the certification statement.

Part B. Statistical Methods.

This information collection does not employ statistical methods.