

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 signed into law 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 (75 FR 41726) to require non-grandfathered group health plans and non-grandfathered group and individual 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), which guidelines HRSA adopted and released on August 1, 2011 (the HRSA Guidelines). Under section 2713 of the PHS Act, its implementing regulations, and the HRSA Guidelines, recommended preventive services required to be covered without cost sharing by applicable plans and coverage include certain contraceptive services.

On August 3, 2011, the Departments amended the 2010 interim final rules (76 FR 46621) (2011 interim final rule amendments) 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 consistent with the HRSA Guidelines. The 2011 interim final rule amendments specified a definition of religious employer. HRSA exercised its authority in the HRSA 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 15, 2012, the Departments published final regulations (77 FR 8725) that adopted the definition of religious employer in the 2011 interim final rule amendments without modification (2012 final regulations) and issued guidance establishing a one year

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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 (78 FR 8456) 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.

After consideration of the comments, the Departments published final regulations on July 2, 2013 (78 FR 39870) (2013 final regulations). A contemporaneously issued Department of Health and Human Services (HHS) guidance document extended the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments against qualifying employers, group health plans, and associated group health insurance coverage to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This 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 the 2013 final regulations. This self-certification form was provided for use with the accommodations under the 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 2013 final

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regulations also provide that the third party administrator or 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 Departments published interim final regulations on August 27, 2014 (79 FR 51092) (2014 interim final regulations), which amended the 2013 final regulations in light of the United States Supreme Court’s interim order in connection with an application for an injunction in *Wheaton College v. Burwell* (Wheaton interim order). The interim final regulations provided that an eligible organization that has a religious objection to providing contraceptive coverage may submit a notification to HHS as an alternative to submitting the EBSA Form 700 to the eligible organization’s health insurance issuer or third party administrator. The 2014 interim final regulations 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 *Wheaton* order.

The Departments published proposed regulations on August 27, 2014 (79 FR 51118) (2014 proposed regulations), which proposed potential changes to the definition of “eligible organization” in light of the United States Supreme Court’s decision in *Burwell v. Hobby Lobby Stores, Inc.* The decision held that closely held for-profit corporations qualified for an exemption under the Religious Freedom Restoration Act from the requirement to provide contraceptive coverage because the owners had religious objections to such coverage and there was a less restrictive means of furthering the law’s interest, specifically, the accommodation the Government provided to non-profit organizations with religious objections.

The final regulations titled “Coverage of Certain Preventive Services Under the Affordable Care Act” modify the Departments’ 2013 final regulations in light of the Supreme Court’s decision in *Burwell v. Hobby Lobby Stores, Inc.* Under these final regulations, qualifying closely held, for-profit entities may now avail themselves of the accommodation to effectively exempt them from the otherwise applicable requirement to cover certain contraceptive services. This accommodation was previously available only to non-profit eligible organizations. The final regulations also finalize the 2014 interim final regulations that permit an eligible organization to notify HHS directly that it will not contract, arrange, pay for, or refer all or a subset of, contraceptive services. To avoid contracting, arranging, paying, or referring for contraceptive coverage, an organization seeking to be treated as an eligible organization under the final regulations may self-certify (by using EBSA Form 700), prior to the beginning of the first plan year

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to which an accommodation is to apply, that it meets the definition of an eligible organization. The self-certification must be executed by an authorized representative of the organization. The self-certification will not be submitted to any of the Departments. The organization must maintain the self-certification in its records in a manner consistent with ERISA section 107 and make it available for examination upon request. The eligible organization must provide a copy of its self-certification to each health insurance issuer that would otherwise provide such coverage in connection with the health plan (for insured group health plans or student health insurance coverage). The issuer that receives the self-certification must provide for separate payments for contraceptive services for plan participants and beneficiaries (or students and dependents). For a self-insured group health plan, the self-certification must be provided to its third party administrator. An eligible organization may also submit a notification to HHS as an alternative to submitting the EBSA Form 700 to the eligible organization's health insurance issuer or third party administrator.

A health insurance issuer or third party administrator providing or arranging payments for contraceptive services for participants and beneficiaries in plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations must provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments. The notice must be provided contemporaneously with (to the extent possible) but separate from any application materials distributed in connection with enrollment (or re-enrollment) in group or student health coverage that is effective on the first day of each applicable plan year, and must specify that contraceptive coverage will not be funded or administered by the eligible organization but that the issuer or third party administrator, as applicable, will separately arrange or provide payments for contraceptive services. The notice must also provide contact information for the issuer or third party administrator for questions and complaints. To satisfy the notice requirement, issuers and third party administrators may use the model language set forth in the 2013 final regulations or substantially similar language.

The final regulations require each closely held, for-profit entity seeking to be treated as an eligible organization to provide notification that it will not act as the plan administrator or claims administrator with respect to, or contribute to the funding of, coverage of all or a subset of contraceptive services. Issuers and third party administrators providing payments for contraceptive services for participants and beneficiaries in plans of eligible organizations are required to meet the notice requirements as set forth in the 2013 final regulations. The Department anticipates that approximately 87 closely held for-profit employers will opt for this accommodation. The final regulations allow eligible organizations to notify an issuer or third party administrator that it will not contract, arrange, pay for, or refer contraceptive services

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based on a religious objection, by using EBSA Form 700, as set forth in the 2013 final regulations. In addition, the final regulations continue to permit an alternative process, consistent with the Supreme Court's Wheaton interim order, under which an eligible organization can notify the Secretary of HHS that it will not contract, arrange, pay for, or refer contraceptive services based on a religious objection, as originally permitted under the August 2014 interim final regulations.

All eligible organizations, whether they are non-profit or closely held for-profit entities, will have the option of providing a self-certification to the issuers or third party administrators of their group health plans (or issuers of their student health plans) or providing a notification to the Department. For the purpose of estimating burdens, in order to avoid double-counting, the Department is assigning the burden for the self-certification (EBSA Form 700 approved under OMB Control Number 1210-0152) to eligible closely held for-profit entities and the burden for notification to HHS (approved under OMB control number 1210-0150) to eligible non-profit organizations. The Department previously estimated that at least 122 for-profit entities will be eligible for the accommodation and provide the self-certification to their issuers or third party administrators or notification to HHS.

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. However, an entity is not required to avail itself of this process in order to qualify as a closely-held for-profit entity.

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.*

Health insurance issuers and third party administrators will need the self-certification provided by organizations seeking to be treated as an eligible organization, or the notification provided by HHS or DOL based on notification to HHS by the eligible organization, in order to make, or arrange for, separate payments for contraceptive services to participants and beneficiaries (or student enrollees and covered dependents) eligible for such coverage. The notices sent by issuers and third party administrators will inform plan participants and beneficiaries (or student enrollees and covered dependents) of the availability of such payments.

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 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.*

Some eligible organizations may be small entities; however, the administrative cost related to the self-certification is low.

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 eligible organizations do not provide the self-certification to issuers and third party administrators or notice to HHS, issuers and third party administrators will not be able to make or arrange for separate payments for contraceptive services. If issuers and third party administrators do not send notices to enrollees, plan participants and beneficiaries (or student enrollees and covered dependents) will not have access to separate payments for contraceptive services without cost sharing.

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;*

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- *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.*

There is no other collection for similar information, so there is no duplication of efforts.

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 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 Departments received comments that HHS underestimated the number of closely held for-profit entities that may be eligible organizations and may seek an accommodation. Some commenters stated that it would be difficult to estimate this number. One commenter noted that in 2011, there were about 2.8 million establishments

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organized as S-corporations with about 28 million employees. The commenter estimated that about 1.3 million S-corporations offer health insurance to their employees and, based on the above data, objection rates of 1% of S-corporations would result in 13,000 objecting firms, an objection rate of 2% would result in 26,000 objecting firms and an objection rate of 5% would result in 65,000 objecting firms. However, the Departments have no indication that such large numbers of closely held for-profit entities will seek the accommodation. The Departments also note that the definition of a qualifying closely held for-profit entity adopted in the final regulations differs from the definition of an S-corporation. Based on litigation, the Department had previously estimated that 71 closely held for-profit entities would seek the accommodation. Based on updated litigation information and communication received by the Department, the Department is revising the estimate to 87.

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.*

Not applicable.

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*

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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.*

Based on numbers anticipated from current litigation and communication with HHS, the Department assumes that the likely number of closely held for-profit entities that will seek an accommodation, and the number of issuers and third party administrators impacted by the final regulations to be 87. Average labor costs (including fringe benefits) used in the burden estimates are calculated using data available from the Bureau of Labor Statistics.

Self-Certification or Notification to HHS

Each organization seeking to be treated as an eligible organization and that chooses the self-certification process will self-certify, prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization and that it objects to providing contraceptive coverage on religious grounds. The self-certification must be executed by an authorized representative of the organization. The self-certification will not be submitted to any of the Departments. The organization must maintain the self-certification in its records in a manner consistent with ERISA section 107 and make it available for examination upon request. The eligible organization must provide a copy of its self-certification to a health insurance issuer that would otherwise provide such coverage in connection with the health plan for insured group health plans or student health insurance coverage, or to the third party administrator, in the case of self-insured coverage. The self-certification must be executed once. A copy of the self-certification must be provided to a new health insurance issuer or third party administrator if the eligible organization changes issuers or third party administrators. Alternatively, each eligible organization may notify the Secretary of HHS that it meets the definition of an eligible organization and that it objects to providing contraceptive coverage on religious grounds.

The Department is anticipating that 87 closely held for-profit entities will seek an accommodation. It is assumed that, for each eligible organization, clerical staff will

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gather and enter the necessary information, send the self-certification or notice to the issuer or third party administrator or to HHS, and retain a copy for recordkeeping, a manager and legal counsel will review it, and a senior executive will execute it. It is estimated that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per hour, 10 minutes for a manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127 per hour, and 5 minutes for a senior executive at a cost of \$121 per hour) to execute the self-certification or notification to HHS. The self-certification or notification to HHS may be electronically transmitted at minimal cost or mailed to the issuer or third party administrator or to HHS. Therefore, the total annual burden for preparing and providing the information in the self-certification or notification to HHS is estimated to be approximately \$53 for each eligible organization. Based on the estimate of 87 affected entities and the individual burden estimate of \$53, the Department estimates the total hour burden to be 72.5 hours with an equivalent cost of \$4,611. As HHS and the Department of Labor share jurisdiction, they are splitting the hour burden so each will account for 36.25 burden hours with an equivalent cost of \$2,305.50, with a total of approximately 44 respondents.

Notice of Availability of Separate Payments for Contraceptive Services

A health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in the coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may use the model language set forth in the 2013 final regulations or substantially similar language.

As mentioned, HHS is anticipating that at least 122 non-profit and 87 closely held for-profit entities will seek an accommodation. It is unknown how many issuers and third party administrators provide health insurance coverage or services in connection with the group health plans of eligible organizations (or will make separate payments for contraceptive coverage for participants and beneficiaries in self-funded plans), but HHS will assume at least 209. The Department estimates that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$30 per hour) and 15 minutes of management review (at \$102 per hour) to prepare the notice. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately \$55.50. The total burden for all issuers and third party

administrators will be 261.25 hours, with an equivalent cost of \$11,599.50. As the Department of Labor and HHS share jurisdiction they are sharing the hour burden equally so each will account for 130.63 burden hours with an equivalent cost of \$5,799.75, with a total of approximately 105 respondents.

Letter to HHS Regarding Ownership Structure

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. However, an entity is not required to avail itself of this process in order to qualify as a closely-held for-profit entity.

The Departments believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. In addition, it appears based on available information that the definition adopted in these final regulations includes all of the for-profit entities that have, as of the date of issuance of these regulations, challenged the contraceptive coverage requirement in court. Therefore, the Departments anticipate that fewer than 10 entities will submit a letter to HHS. Under 5 CFR 1320.3(c)(4), this provision is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

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.)*

Issuers and third party administrators are expected to incur capital costs to fulfill the requirements to provide written notices. Eligible organizations are expected to incur capital costs to fulfill the requirements related to the self-certification or notification to HHS. Notices to enrollees and self-certifications or notifications to HHS may be sent electronically at minimal cost or by mail. For purposes of this analysis, it is assumed that all self-certifications or notifications to HHS, and notices to enrollees will be mailed. It is estimated that each self-certification or notice to HHS or notice to enrollees 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 to HHS or notice to enrollees sent via mail is estimated to be \$0.54. The total cost for mailing self-certifications or notices to HHS is \$46.98. Because this will be split with the Department of Labor, the HHS burden is \$23.49, with approximately 44 respondents.

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),*

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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 12 or 14.*

This is a new information collection.

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.