

Supporting Statement – Part A
Coverage of Certain Preventive Services Under the Affordable Care Act
(CMS-10459)

A. Background

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 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 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).¹ 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 organization need not use any particular form, and must indicate only the basis on which it qualifies for the accommodation, as well as the type of plan it offers and contact information for the plan’s insurers and third party administrators. If the eligible organization objects only to a subset of range of contraceptive services, it should also specify which specific methods to which it objects. If the eligible organization elects to opt out using this procedure, the Departments of Labor and HHS notify its issuers and third party administrators of their obligation to provide separate contraceptive coverage. 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.² 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.

B. Justification

1. Need and Legal Basis

1 134 S. Ct. 2806 (2014).

2 134 S. Ct. 2751 (2014).

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 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. For insured plans, 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.

As an alternative to using the EBSA Form 700, an eligible organization may also submit a notification to HHS. There is no particular form for this notification; the organization must instead indicate the basis on which it qualifies for the accommodation, the type of plan it offers, and contact information for the plan's insurers and TPAs. If an organization opts out using this procedure, the Departments of HHS and Labor notify the organization's issuers and TPAs of their obligations to provide separate contraceptive coverage.

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 HHS. For the purpose of estimating burdens, in order to avoid double-counting, HHS is assigning the burden for the self-certification (EBSA Form 700) to eligible closely held for-profit entities and the burden for notification to HHS (approved under OMB control number 0938-1248) to eligible non-profit organizations. We 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.

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 contemporaneous 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.

Finally, 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. Information Users

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. Use of Information Technology

The final regulations do not limit the ability of affected eligible organizations to furnish the self-certification or notice to HHS electronically.

4. Duplication of Efforts

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

5. Small Businesses

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

6. Less Frequent Collection

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. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A Federal Register notice was published on August 27, 2014 (79 FR 51123), providing the public with a 60-day period to submit written comments on these information collection requirements (ICRs).

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 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. HHS had previously estimated that 71 closely held for-profit entities would seek the accommodation. Based on updated information and communication received by HHS, HHS is revising the estimate to 87.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these ICRs.

10. Confidentiality

Privacy of the information provided will be protected to the extent provided by law.

11. Sensitive Questions

These ICRs involve no sensitive questions.

12. Burden Estimates (Hours & Wages)

Based on current information, HHS 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 needs to be executed once. A copy of the self-certification needs to 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. There is no particular form for this notification; the organization must indicate the basis on which it qualifies for the accommodation, the type of plan it offers, and contact information for the plan's insurers and TPAs. If an organization opts out using this procedure, the Departments of HHS and Labor notify the organization's issuers and TPAs of their obligations to provide separate contraceptive coverage.

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

Table 1. Estimated Annualized Burden for Self-Certification or Notification to HHS

Notice	Number of respondents	Number of responses	Estimated Burden Hours per Respondent	Total Estimated Annual Burden Hours	Estimated Burden Cost Per Respondent	Total Estimated Annual Cost
Self-Certification or Notification to HHS	44	1	0.83	36.25	\$53	\$2,305.50

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. It is estimated 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 splitting the hour burden so each will account for 130.63 burden hours with an equivalent cost of \$5,799.75, with a total of approximately 105 respondents.

Table 2. Estimated Annualized Burden for Notice of Availability of Contraceptive Coverage

Notice	Number of respondents	Estimated Burden Hours per Respondent	Total Estimated Annual Burden Hours	Estimated Burden Cost Per Respondent	Total Estimated Annual Labor Cost
Notice of Availability of Separate Payments for Contraceptive Services	105	1.25	130.63	\$55.50	\$5,799.75

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. Capital Costs

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. This will be split with the Department of Labor; the HHS burden is \$23.49, with approximately 44 respondents.

14. Cost to Federal Government

There is no cost to the federal government.

15. Changes to Burden

This is a new collection of information.

16. Publication/Tabulation Dates

There are no publication or tabulation dates associated with these ICRs.

17. Expiration Date

There is no expiration date for this collection requirement.