Supporting Statement – Part A
Coverage of Certain Preventive Services Under the Affordable Care Act
(CMS-10535)

A. Background

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 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 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.

B. Justification.

1. Need and Legal Basis

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.

The interim final regulations amend the EBSA Form 700 ICR. HHS 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.

2. Information Users

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. Use of Information Technology

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. Duplication of Efforts

The information collection does not require duplicative information.

5. Small Businesses

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.

6. Less Frequent Collection

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. Special Circumstances

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. Federal Register/Outside Consultation

As discussed in Item 1 above, HHS is revising this ICR pursuant to the emergency PRA clearance procedures set forth under 5 CFR 1320.13. The OMB emergency approval expires on February 28, 2015. Therefore, contemporaneously with the publication of

these interim final regulations, the Department has published a notice elsewhere in today's issue of the Federal Register informing the public of its intention to extend the OMB approval for three years. The notice solicits comments on the revisions to the ICR and provides the public with 60 days to comment as required by 5 CFR 1320.8(d).

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 and Wages)

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.

HHS does not know the total number of organizations that would seek an accommodation. HHS 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. HHS 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, HHS assumes that 122 eligible organizations will seek accommodation under the interim final regulations. In order to complete this task, HHS 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.[1] HHS 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. HHS 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 110 hours with an equivalent cost of $6,425.

Table 1. Estimated Annualized Burden for the Notification

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	122	1	0.83	110	$53	$6425

13. Capital Costs

HHS estimates that each self-certification or notice to HHS will require $0.49 in postage and $0.0**5** 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, HHS 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.

14. Costs to the Federal Government

There is no cost to the federal government.

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

15. Changes to Burden

The information collection has been revised by new interim final regulations.

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.