

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 (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. We refer to the two statutes collectively as the “Affordable Care Act”. The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans. The PHS Act sections incorporated by these references are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. Among these services are women’s preventive health services, as specified in guidelines supported by the Health Resources and Services Administration (HRSA Guidelines). As authorized by the current regulations, and consistent with the HRSA Guidelines, group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the otherwise applicable requirement to cover certain contraceptive services.

The final regulations “Coverage of Certain Preventive Services Under the Affordable Care Act” published by the Departments of Health and Human Services (HHS), the Treasury, and Labor, (collectively, the Departments) simplify and clarify the religious employer exemption. In addition, the final regulations establish accommodations that provide women with access to contraceptive services, without cost sharing, while simultaneously protecting certain nonprofit religious organizations with religious objections to contraceptive coverage from having to contract, arrange, pay, or refer for such coverage.

B. Justification

1 . Need and Legal Basis

An organization seeking to be treated as an eligible organization under the final regulations, to avoid contracting, arranging, paying, or referring for contraceptive coverage, must 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. 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.

The proposed regulations sought comments on a notice of availability of contraceptive coverage. The final regulations instead direct a health insurance issuer providing payments for contraceptive services for participants and beneficiaries in plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations 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 provided contemporaneous with (to the extent possible) but separate from any application materials distributed in connection with enrollment (or re-enrollment) in group 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 will separately arrange or provide payments for contraceptive services. The notice must also provide contact information for the issuer for questions and complaints. To satisfy the notice requirement, issuers may use the model language set forth in the final regulations or substantially similar language.

2. Information Users

Health insurance issuers will need the self-certification provided by eligible organizations seeking to be treated as an eligible organization in order to make separate payments for contraceptive services to participants and beneficiaries eligible for such coverage. The notices sent by issuers will inform plan participants and beneficiaries of the availability of such payments.

3. Use of Information Technology

Eligible organizations are expected to provide the self-certification to issuers electronically.

4. Duplication of Efforts

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

5. Small Businesses

Small businesses are not affected by this collection.

6. Less Frequent Collection

If eligible organizations do not provide the self-certification to issuers, and if issuers do not send the notices, plan participants and beneficiaries will not have access to contraceptive coverage.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice was displayed as part of a notice of proposed rulemaking on February 1, 2013.

Comments addressing the self-certification generally approved of the approach proposed by the Departments, but some commenters suggested that stronger protections were needed to promote oversight, enforcement, and transparency and to prevent abuse. For example, some commenters recommended requiring eligible organizations to file their self-certifications with the Departments and making such records available to the public. Other commenters argued that the act of self-certification would infringe on the First Amendment right of free speech. The final regulations do not require the self-certification to be submitted to any of the Departments. An eligible organization must simply maintain the self-certification (executed by an authorized representative of the organization) in its records, in a manner consistent with the record retention requirements under section 107 of ERISA, and make the self-certification available for examination upon request. The Departments believe that the requirement to make the self-certification available for examination upon request appropriately balances regulators', issuers', and plan participants and beneficiaries' (and student enrollees and their covered dependents') interest in verifying compliance and eligible organizations' interest in avoiding undue inquiry into their character, mission, or practices. Further, the Departments do not believe that the self-certification standard infringes on freedom of speech.

One commenter stated that the cost of preparing and sending the notices may be greater than estimated, but did not provide an estimate. HHS believes that using the model language provided in the final regulations will help minimize costs and declines to revise the estimate.

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)

HHS sought comments in the proposed regulations, but did not receive any information that would allow for an estimate of the number of organizations that would seek to be treated as eligible organizations or an estimate of the number of health insurance issuers that would provide separate payment for contraceptive services. HHS is, nevertheless, seeking OMB approval for the following ICRs consistent with the Paperwork Reduction Act of 1995. The burden estimates will be updated in the future when more information is available. Average labor costs (including fringe benefits) used in the burden estimates are calculated using data available from the Bureau of Labor Statistics.

Self-Certification

Each organization seeking to be treated as an eligible organization 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. 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. The self-certification needs to be executed once. A copy of the self-certification needs to be provided to a new health insurance issuer if the eligible organization changes issuers.

HHS is unable to estimate how many organizations will seek an accommodation. Therefore the burden for only one eligible organization is estimated. It is assumed that, for each eligible organization, clerical staff will gather and enter the necessary information, send the self-certification electronically to the issuer 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 \$30.64 per hour, 10 minutes for a manager at a cost of \$55.22 per hour, 5 minutes for legal counsel at a cost of \$83.10 per hour, and 5 minutes for a senior executive at a cost of \$112.43 per hour) to execute the self-certification. The certification may be electronically transmitted to the issuer at minimal cost. Therefore, the total annual burden for preparing and providing the information in the self-certification is estimated to be approximately \$41 for each eligible organization.

Table 1. Estimated Annualized Burden for Self-Certification

Notice	Number of respondents	Number of responses	Total Estimated Annual Burden Hours	Total Estimated Annual Cost
Self-Certification	1	1	0.83	\$41

Notice of Availability of Separate Payments for Contraceptive Services

A health insurance issuer providing 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 group 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 may use the model language set forth in the final regulations or substantially similar language.

It is unknown how many issuers provide health insurance coverage in connection with insured plans of eligible organizations. Therefore, the burden for only one issuer is estimated. It is estimated that each issuer will need approximately 1 hour of clerical labor (at \$31.64 per hour) and 15 minutes of management review (at \$55.22 per hour) to prepare the notices for a total cost of approximately \$44. It is estimated that each notice will require \$0.46 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail is estimated to be \$0.51.

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

Notice	Number of respondents	Total Estimated Annual Burden Hours	Total Estimated Annual Labor Cost	Estimated Materials and Mailing Cost per Notice
Notice of Availability of Separate Payments for Contraceptive Services	1	1.25	\$44	\$0.51

13. Capital Costs

Eligible organizations and issuers are not expected to incur capital costs to fulfill these requirements.

14. Cost to Federal Government

There is no cost to the federal government.

15. Changes to Burden

Not applicable.

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.

18. Certification Statement

There are no exceptions to the certification.