

Supporting Statement – Part A
Coverage of Certain Preventive Services Under the Affordable Care Act
(CMS-10653/OMB Control Number: 0938-1344)

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 (HHS), 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 health insurance issuers offering 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 (HRSA Guidelines).

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 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 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 2014 interim final

1 134 S. Ct. 2806 (2014).

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 also 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.

On July 14, 2015, the Departments published final regulations (80 FR 41318) (2015 final rules) that modified 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 avail themselves of the accommodation to effectively exempt their plans 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 finalized 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.

On October 13 2017, the Departments published two interim final regulations "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" (82 FR 47792) and "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" (82 FR 47838) (2017 interim final rules) that expand the exemption to include additional entities and persons that object based on sincerely held religious beliefs or moral convictions. With respect to employers, the expanded exemption in these rules covers employers that have sincerely held religious beliefs or moral convictions objecting to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling as specified in the HRSA Guidelines. As in the previous rules, institutions of higher education that arrange student health insurance coverage will continue to be treated similar to the way employers are treated for the purposes of such plans being exempt. The interim final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union) that object based

² 134 S. Ct. 2751 (2014).

on sincerely held religious beliefs or moral convictions to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling. The interim final rules extend the exemption to group and individual market health insurance issuers that hold sincerely held religious or moral objections in certain circumstances. The interim final rules also leave the accommodation process in place as an optional process for objecting entities who wish to use it voluntarily. Eligible organizations can revoke at any time the accommodation process if participants and beneficiaries receive written notice of such revocation from the issuer or third party administrator in accordance with guidance issued by the Secretary,³ and if the accommodation process is currently being utilized, such revocation will be effective on the first day of the first plan year that begins on or after thirty days after the date of revocation. On November 15, 2018, the Departments published two final rules “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” (83 FR 57536) and “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” (83 FR 57592) that finalized the provisions of the 2017 interim final regulations.

B. Justification

1 . Need and Legal Basis

An entity seeking to be treated as an eligible organization 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. 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 the plan’s third party administrator. An eligible organization 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.

A health insurance issuer or third party administrator providing or arranging payments for contraceptive services for participants and beneficiaries in plans (or for student enrollees and covered dependents in student health insurance coverage) of eligible organizations must

³ Guidance was issued on November 30, 2017, available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf>. See Appendix I.

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.

To the extent provided under the applicable regulations governing the accommodation, eligible organizations can revoke at any time the accommodation if participants and beneficiaries are provided written notice of such revocation by the issuer or third party administrator in accordance with guidance issued by the Secretary, and such revocation will be effective on the first day of the first plan year that begins on or after thirty days after the date of revocation.

2. Information Users

These information collection requirements (ICRs) include a self-certification that may be submitted to health insurance issuers and third party administrators and a model notice that may be submitted to HHS by eligible organizations. In addition, they include a notice of availability of separate payments for contraceptive services and a revocation notice to be sent to enrollees by health insurance issuers and third party administrators, should the accommodation rules in effect so provide.

Health insurance issuers and third party administrators will need the self-certification provided by entities seeking to be treated as eligible organizations, or the notification provided by HHS or the Department of Labor 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 notice of availability of separate payments for contraceptive services 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. Should the accommodation rules in effect so provide, the revocation notices sent by issuers and third party administrators of organizations that no longer want to use the accommodation process will inform plan participants and beneficiaries (or student enrollees and covered dependents) that the separate payments for contraceptive services will no longer be available.

3. Use of Information Technology

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

4. Duplication of Efforts

There is no duplication of efforts for these ICRs.

5. Small Businesses

Some eligible organizations may be small entities. However, the administrative cost related to the self-certification or notification to HHS 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 of the availability of separate payments for contraceptive services, plan participants and beneficiaries (or student enrollees and covered dependents) will not be aware that they have access to separate payments for contraceptive services without cost sharing. If eligible organizations seeking to revoke the accommodation do not send the revocation notices, plan participants and beneficiaries (or student enrollees and covered dependents) will not be aware that separate payments for contraceptive services will no longer be available.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A 60-day notice was published in the Federal Register on August 6, 2021 (86 FR 43255), providing the public with a 60-day period to submit written comments on these ICRs. One comment was received. A summary of the comment and response is included in Appendix II. The 30-day notice published in the Federal Register on November 19, 2021 (86 FR 64940), providing the public with an additional 30-day period to submit written comments on these ICRs.

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)

Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics (BLS).⁴

TABLE 1: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hr.)	Fringe Benefits and Overhead (\$/hr.)	Adjusted Hourly Wage (\$/hr.)
Administrative Assistant	43-6014	\$19.43	\$19.43	\$38.86
Compensation and Benefits Manager	11-3111	\$65.94	\$65.94	\$131.88
General and Operations Manager	11-1021	\$60.45	\$60.45	\$120.90
Senior Executive	11-1011	\$95.12	\$95.12	\$190.24
Lawyer	23-1011	\$71.59	\$71.59	\$143.18

Self-Certification or Notification to HHS

Each organization seeking to be treated as an eligible organization for purposes of the optional accommodation process and that chooses the self-certification method 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 or moral 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

⁴ May 2020 National Occupational Employment and Wage Estimates United States found at https://www.bls.gov/oes/current/oes_nat.htm. To account for fringe and overhead, HHS is using 100% of the hourly labor wage for each specific BLS occupation code.

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 or moral grounds.

The Departments estimate that approximately 9 entities would seek the accommodation for the first time and either self-certify or send a notification to HHS and 100 entities will continue the voluntary accommodation.

For each entity that chooses to opt into the accommodation process, HHS assumes that clerical staff will need 30 minutes (at \$38.86 per hour) to gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS, and keep records, a compensation and benefits manager will need 10 minutes (at \$131.88 per hour) and inside legal counsel will need 5 minutes (at \$190.24 per hour) to review the self-certification or notice to HHS, and a senior executive will need 5 minutes (at \$190.24 per hour) to execute it. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS and recordkeeping will be approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$69.⁵

The total hour burden will be approximately 7.5 hours with an equivalent cost of approximately \$623 for 9 entities. As the Department of Labor and HHS share jurisdiction they will split the hour burden so each will account for approximately 3.75 burden hours with an equivalent cost of approximately \$311.

Table 2. Estimated Annualized Burden for Self-Certification or Notification to HHS

Notice	Number of respondents	Estimated Number of Responses	Estimated Burden Hours per Respondent	Total Estimated Annual Burden Hours	Estimated Burden Cost Per Respondent	Total Estimated Annual Labor Cost
Self-Certification or	5	5	0.83	3.75	\$69.20	\$311.38

⁵ 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.

Notification to HHS						
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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.

HHS anticipates that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$38.86 per hour) and 15 minutes of management review (at \$120.90 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately \$69. The total burden for all issuers or third party administrators will be 136.25 hours, with an equivalent cost of approximately \$7,530. As the Department of Labor and HHS share jurisdiction, they are splitting the hour burden so each will account for approximately 68 burden hours with an equivalent cost of approximately \$3,765, with approximately 55 respondents.

Table 3. Estimated Annualized Burden for Notice of Availability of Contraceptive Coverage

Notice	Number of respondents	Estimated Number of Responses	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	55	595,307	1.25	68.13	\$69.09	\$3,765.13

Contraceptive Services						
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Notice of Revocation of Accommodation

If the accommodation rules in effect so provide, an eligible organization may revoke its use of the accommodation process and its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as specified in guidance issued by the Secretary. The Departments expect that entities that wished to do so have already sent the notice, and that no additional entities will avail themselves of, and subsequently revoke, use of the accommodation process. Therefore, no new entities are expected to incur this cost in the future.

13. Capital Costs

Self-Certification or Notification to HHS

HHS estimates that each self-certification or notice to HHS will require \$0.55 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 \$0.60. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The estimated total cost for sending the self-certifications or notices to HHS by mail is approximately \$3 for 5 entities. As the Department of Labor and HHS share jurisdiction they are splitting the cost burden so each will account for approximately \$1.5 of the cost burden.

Notice of Availability of Separate Payments for Contraceptive Services

In the 2018 final regulations, the Departments estimated that 2,376,000 persons will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and the additional 9 entities that will newly opt into the accommodation⁶. The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all plan participants and beneficiaries. Among persons covered by plans, it is estimated that approximately 50.1% are policyholders and 49.9% are dependents⁷. For 109 entities, the total number of notices is estimated to be 1,190,613. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically.⁸

6 83 FR 57583

7 “Health Insurance Coverage Bulletin” Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/healthand-welfare/health-insurance-coverage-bulletin-2015.pdf>.

8 According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the

Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require \$0.55 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.60. The total cost for sending approximately 551,254 notices by mail is approximately \$330,752. As the Department of Labor and HHS share jurisdiction they are splitting the cost burden so each will account for \$165,376 of the cost burden.

14. Cost to Federal Government

There is no cost to the federal government.

15. Changes to Burden

There is a reduction in burden of 109 hours due to the assumption that no new revocation notices will be sent.

16. Publication/Tabulation Dates

There are no plans to publish the outcome of the data collection.

17. Expiration Date

The expiration date will be displayed on the first page of each instrument (top, right-hand corner).

proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.