**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). 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 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]](#footnote-2) The 2014 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 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]](#footnote-3) 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 regulations) 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 expanded 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 covered 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 continued to be treated similar to the way employers are treated for the purposes of such plans being exempt. The interim final rules also exempted group health plans sponsored by an entity other than an employer (for example, a union) that object based 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 further extended the exemption to health insurance issuers that hold sincerely held religious or moral objections in certain circumstances. The interim final rules also left the accommodation process in place as an optional process for objecting entities who wish to use it voluntarily. Additionally, the interim final rules provided that eligible organizations could revoke at any time the accommodation process if participants and beneficiaries received written notice of such revocation from the issuer or third party administrator in accordance with guidance issued by the Secretary,[[3]](#footnote-4) and if the accommodation process was currently being utilized, such revocation would be effective on the first day of the first plan year that begins on or after thirty days after the date of revocation.[[4]](#footnote-5)

After consideration of the comments and feedback received from stakeholders on the 2017 interim final rules, the Departments published two final regulations “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” and “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” (2018 final regulations). These rules finalize the provisions of the 2017 interim final rules, including maintaining the accommodation process as an optional process for entities that qualify for the exemption. The Departments modified the regulations governing when an entity, that was using or will use the accommodation, can revoke the accommodation and operate under the exemption. The modifications set forth a transitional rule as to when entities currently using the accommodation may revoke it and use the exemption by giving 60-days’ notice. The modifications also express a general rule that, in plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an organization eligible for the accommodation may revoke its use of the accommodation process effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

**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 its 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 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.

The 2018 final regulations provide a transitional rule that allows entities currently using the accommodation to revoke it and use the exemption by giving 60-days’ notice pursuant to PHS Act section 2715(d)(4) and §2590.715-2715(b). For plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an organization eligible for the accommodation may revoke its use of the accommodation process effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the 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.

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. 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

The burden related to the notice to HHS was previously approved under OMB Control Number 0938–1248 (CMS-10535, Employer Notification Request to HHS of its Objection to Providing Contraceptive Services) and the burden related to the self-certification (EBSA Form 700) and notice of availability of separate payments for contraceptive services was previously approved under OMB control number 0938-1292 (CMS-10459, Coverage of Certain Preventive Services Under the Affordable Care Act). HHS requested and received, pursuant to the emergency PRA clearance procedures set forth under 5 CFR 1320.13, a new OMB control number 0938-1344 (CMS-10653, Coverage of Certain Preventive Services Under the Affordable Care Act) that contains the approval for the new ICRs contained in the 2017 interim final rules as well as the related requirements currently approved under 0938-1292 and 0938-1248. HHS is requesting review and approval of the burden related to the ICRs contained in the 2018 final regulations under OMB control number 0938-1344. In an effort to consolidate the number of information collection requests, we will formally discontinue the control numbers 0938-1292 and 0938-1248.

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 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 notice was published in the Federal Register on November 8, 2017 (82 FR 51843), providing the public with a 60-day period to submit written comments on these ICRs.

We received 3 comments, as summarized in Appendix II. We received one comment opposing the ICRs on the basis that implementation of the 2017 interim final rules is preliminarily enjoined. In response to this comment and the injunctions, we revised the ICRs to reflect the fact that they can be used under whichever accommodation rules are in effect.

We also published a notice in the Federal Register on April 30, 2018 (83 FR 17555) providing the public with a 30-day period to submit written comments on these ICRs. No comments were received.

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 data collections 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.[[5]](#footnote-6)

Table 1: National Occupational Employment and Wage Estimates

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| BLS Occupation Title | Occupational Code | Mean Hourly Wage ($/hr) | Fringe Benefits and Overhead ($/hr) | Adjusted Hourly Wage ($/hr) |
| Executive Secretaries and Executive Administrative Assistants | 43-6011 | $27.84 | $27.84 | $55.68 |
| Compensation and Benefits Manager | 11-3111 | $61.01 | $61.01 | $122.02 |
| Legal Counsel | 23-1011 | $67.25 | $67.25 | $134.50 |
| Senior Executive | 11-1011 | $93.44 | $93.44 | $186.88 |
| General and Operations Managers | 11-1021 | $58.70 | $58.70 | $117.40 |

Self-Certification or Notification to HHS

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under these final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations (80 FR 41318).

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party administrator). HHS assumes that, among the 209 entities the Departments estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes that clerical staff for each eligible organization will 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.[[6]](#footnote-7) 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 50 minutes (30 minutes of clerical labor at a cost of $55.68 per hour, 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour, 5 minutes for legal counsel at a cost of $134.50 per hour, and 5 minutes by a senior executive at a cost of $186.88 per hour) 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 of approximately $74.96 for a total hour burden of approximately 7.5 hours and an associated equivalent cost of approximately $675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so that each will account for approximately 3.75 burden hours with an equivalent cost of approximately $337.

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 Notification to HHS under the 2018 final regulations | 5 | 1 | 0..83 | 3.75 | $74.96 | $337.31 |

Notice of Availability of Separate Payments for Contraceptive Services

As required by the July 2015 final regulations (80 FR 41318), a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or 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 or student 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, but are not required to, use the model language previously provided by HHS or substantially similar language.

As mentioned, HHS is anticipating 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 $55.68 per hour) and 15 minutes of management review (at $117.40 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 associated cost of approximately $85.03. The total burden for all 109 issuers or third party administrators will be 136 hours, with an associated cost of approximately $9,268. As DOL and HHS share jurisdiction, they are splitting the burden each will account for 68 burden hours with an associated cost of $4,634, with approximately 55 respondents.

The Departments estimate that approximately 2,180,000 plan participants and beneficiaries will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. We reach this estimate using calculations in which we used 2017 data available to HHS for contraceptive user fees adjustments to estimate that approximately 2,907,000 plan participants and beneficiaries were covered by plans using the accommodation. We further estimated that the 100 entities that previously used the accommodation and will continue doing so will cover approximately 75 percent of the persons in all accommodated plans, based on HHS data concerning accommodated self-insured plans that indicates plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As noted in the 2018 final regulations, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans. The Departments do not have specific data on which plans of which employer sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data.

Based on these assumptions and without better data available, the Departments estimate that previously accommodated entities encompassed approximately 2,907,000 persons; the estimated 100 entities that previously used the accommodation and continue to use it will account for 75 percent of those persons (that is, approximately 2,180,000 persons); and the estimated 109 entities that previously used the accommodation and will now use their exempt status will account for 25 percent of those persons (that is, approximately 727,000 persons). It is not known how many persons will be covered in the plans of the 9 entities we estimate will newly use the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity as the 100 entities encompassing 2,180,000 persons, the Departments estimate that all 109 accommodated entities will encompass approximately 2,376,000 covered persons.

The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all participants and dependents. Among persons covered by insurance plans sponsored by large employers in the private sector, approximately 50.1 percent are participants and 49.9 percent are dependents.[[7]](#footnote-8) For 109 entities, the total number of notices will be approximately 1,190,613. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.[[8]](#footnote-9) Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require $0.50 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 $0.55. The total cost for sending approximately 551,254 notices by mail will be approximately $303,190. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $151,595 of the cost burden.

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 Contraceptive Services under the 2018 final regulations | 109 | 595,307 | 1.25 | 68.13 | $85.03 | $4,634.14 |

 Notice of Revocation of Accommodation

 An eligible organization that now wishes to take advantage of the expanded exemption may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to send the notification; the issuer or third party administrator can send the notice on behalf of the entity. For the purpose of calculating the ICRs associated with revocations of the accommodation HHS assumes that litigating entities that were previously using the accommodation and that will revoke their use of the accommodation fall within the estimated 109 entities that will revoke the accommodation overall.

 HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of $117.40 per hour, 30 minutes for legal counsel at a cost of $134.50 per hour, 1 hour for clerical staff at a cost of $55.68 per hour). The burden per respondent will be 2 hours with an associated cost of approximately $182; for 109 entities, the total hour burden will be 218 hours with an associated cost of approximately $19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an associated cost of approximately $9,899.

 As discussed above, HHS estimates that there are approximately 727,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[[9]](#footnote-10) As before, the Departments use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 364,102 notices will be distributed, of which 168,579 notices will be mailed. HHS estimates that each mailed notice will require $0.50 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 $0.55. The total cost for sending approximately 168,579 notices by mail is approximately $93,545. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 182,051 notices, with an associated cost of approximately $46,772.

Table 4. Estimated Annualized Burden for Notice of Revocation of Accommodation

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 Revocation of Accommodation under the 2017 interim final rules | 109 | 182,051 | 2 | 109 | $181.63  | $9,898.84 |

Table 5: Summary of Estimated Annualized Burdens

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Notice** | **Estimated Number of respondents** | **Estimated Number of Responses** | **Estimated Burden per Respondent (hours)** | **Total Annual Burden (hours)** | **Total Labor Cost of Reporting ($)** | **Estimated Total Cost ($)** |
| Self-Certification or Notices to HHS | 9\* | 5 | 0.83 | 3.75 | $337  | $2  |
| Notice of Availability of Separate Payments for Contraceptive Services | 109\* | 595,307 | 1.25 | 68.13 | $4,634  | $151,208  |
| Notice of Revocation of Accommodation | 109\* | 182,051 | 2.00 | 109 | $9,899  | $45,513 |
| Total | 227\* | 777,367 |  | 180.88 |   | $196,723  |

\*The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and above exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: Postage and material costs are included in Total Cost.

13. Capital Costs

A. Self-Certification or Notification to HHS

HHS estimates that each self-certification or notice to HHS will require $0.50 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 $0.55. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately $2.75 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so that each will account for **$1.38** of the cost burden.

B. Notice of Availability of Separate Payments for Contraceptive Services

The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all participants and dependents. Among persons covered by insurance plans sponsored by large employers in the private sector, approximately 50.1 percent are participants and 49.9 percent are dependents.[[10]](#footnote-11) For 109 entities, the total number of notices will be approximately 1,190,613. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.[[11]](#footnote-12) Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require $0.50 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 $0.55. The total cost for sending approximately 551,254 notices by mail will be approximately $303,190. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $**151,595** of the cost burden.

C. Notice of Revocation of Accommodation

HHS estimates that there are approximately 727,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[[12]](#footnote-13) As before, the Departments use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 364,102 notices will be distributed, of which 168,579 notices will be mailed. HHS estimates that each mailed notice will require $0.50 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 $0.55. The total cost for sending approximately 168,579 notices by mail is approximately $93,545. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 182,051 notices, with an associated cost of approximately **$46,772**.

 **Cost burden for CMS is $198,368.**

14. Cost to Federal Government

There is no cost to the federal government.

15. Changes to Burden

The burden related to the 2015 final regulations is currently approved under OMB Control Numbers 0938-1248 and 0938-1292.

Under the 2018 final regulations, the burden related to the self-certification or notice to HHS is reduced by 83.5 hours from 87.25 (currently approved under OMB Control Number 0938-1248 and 0938-1292) to 3.75 due to the reduction in the estimated number of respondents from 105 to 9. The burden related to the notice of availability of separate payments for contraceptive services is reduced by approximately 62.5 hours from 130.63 (currently approved under OMB Control Number 0938-1292) to 68 for the same reason. There is a new burden of 109 hours for the new requirement for the notice of revocation of accommodation.

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).

1. 134 S. Ct. 2806 (2014). [↑](#footnote-ref-2)
2. 134 S. Ct. 2751 (2014). [↑](#footnote-ref-3)
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. [↑](#footnote-ref-4)
4. As of the date of this issuance, judicial decisions have preliminarily enjoined implementation of the 2017 interim final rules. [↑](#footnote-ref-5)
5. May 2016 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. [↑](#footnote-ref-6)
6. For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS. [↑](#footnote-ref-7)
7. “Health Insurance Coverage Bulletin” Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>. [↑](#footnote-ref-8)
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 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. [↑](#footnote-ref-9)
9. In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, the Departments indicated that we do not know the extent to which the number of women in accommodated plans affected by the 2018 final rules overlap with the number of women in plans offered by litigating entities that will be affected by the final rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status. [↑](#footnote-ref-10)
10. “Health Insurance Coverage Bulletin” Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>. [↑](#footnote-ref-11)
11. 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 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. [↑](#footnote-ref-12)
12. In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, the Departments indicated that we do not know the extent to which the number of women in accommodated plans affected by the 2018 final rules overlap with the number of women in plans offered by litigating entities that will be affected by the final rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status. [↑](#footnote-ref-13)