Supporting Statement – Part A
Coverage of Certain Preventive Services Under the Affordable Care Act: Data Submission Requirements to Receive the Federally-facilitated Exchange User Fee Adjustment

A. Background

The Affordable Care Act (Pub. L. 111–148) 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 make sections 2701 through 2728 of part A of title XXVII of the PHS Act applicable to group health plans
Section 1311(d)(5)(A) of the Affordable Care Act contemplates an Exchange charging assessments or user fees to participating issuers to generate funding to support its operations. When operating a Federally-facilitated Exchange (FFE) under section 1321(c)(1), HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the statute to collect and spend such user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget Circular A-25 Revised (Circular A-25R) establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. On March 11, 2013, HHS published the HHS Notice of Benefit and Payment Parameters for 2014, which establishes a user fee for issuers participating in an FFE.

The final rule "Coverage of Certain Preventive Services Under the Affordable Care Act" (78 FR 39870) published by the Departments of Health and Human Services (HHS), the Treasury, and Labor on July 2, 2013, set forth regulations regarding coverage for certain preventive services under section 2713 of the Public Health Service Act. Section 2713 of the Public Health Service Act requires coverage without cost sharing of certain preventive health services, including certain contraceptive services, in non-exempt, non-grandfathered group health plans and health insurance coverage. The final regulations establish rules 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. Eligible organizations are required to self-certify that they are eligible for this accommodation and provide a copy of such self-certification to their third party administrators. The final rules also set forth processes and standards to fund the payments for the contraceptive services that are provided for participants and beneficiaries in self-insured plans of eligible organizations under the accommodation described previously, through an adjustment in the FFE user fee payable by an issuer participating in an FFE.
On August 27, 2014, the Departments of Treasury, Labor, and Health and Human Services (the Departments), published a Notice of Proposed Rulemaking, "Coverage of Certain Preventive Services Under the Affordable Care Act" (79 FR 51118), to propose and seek comments on potential changes to the definition of "eligible organization" in the

Departments' regulations in light of the U.S. Supreme Court's decision in Burwell v. Hobby Lobby Stores, Inc., to ensure that participants and beneficiaries in group health plans (and in student health insurance coverage arranged by institutions of higher education) obtain, without additional cost, coverage of the full range of FDA approved contraceptives, as prescribed by a health care provider, while respecting certain closely held for- profit entities' religious-based objections to contraception.

B. Justification

1. Need and Legal Basis

The final rule at 45 CFR 156.50(d)(2)(i) requires a participating issuer seeking an FFE user fee adjustment to submit to HHS, in the year following the calendar year in which the contraceptive services for which payments were made under the accommodation described previously were provided, identifying information for the participating issuer, each third party administrator, and each self-insured group health plan, as well as the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year under the accommodation. Additionally, the final rule at 45 CFR 156.50(d)(2)(iii) requires the third party administrator to submit to HHS identifying information for the third party administrator, the participating issuer, and each self-insured group health plan, as well as the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year, the total dollar amount payments for contraceptive services, and an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2). HHS needs this information collection to ensure that these FFE user fee adjustments reflect payments for contraceptive services provided under this accommodation and the adjustment is applied to the appropriate participating issuer.

Finally, the final rule under 45 CFR 156.50(d)(2)(ii) also requires third party administrators to submit to HHS a notification that the third party administrator intends for a participating issuer to seek an FFE user fee adjustment, by the later of January 1, 2014, or the 60th calendar day following the date on which the third party administrator receives a copy of a self-certification from an eligible organization. The third party administrator would also be required to submit the expected number of participants and beneficiaries for which it seeks the adjustment as part of this notification. HHS requires this information collection to determine the potential number of submissions provided by third party administrators in order to have the capacity to receive the previously mentioned submissions from applicable participating issuers and third party administrators in the 2015 calendar year.

2. Information Users

CMS will use the data collections from participating issuers and third party administrators to verify the total dollar amount for such payments for contraceptive services provided under this accommodation for the purpose of determining a participating issuer's user fee adjustment. The attestation that the payments for contraceptive services were made in

compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2) will help ensure that the user fee adjustment is being utilized to provide contraceptive services for the self-insured plans in accordance with the previously noted accommodation.

3. Use of Information Technology

HHS anticipates that participating issuers in the FFE who seek a user fee adjustment and third party administrators with respect to which an FFE user fee adjustment is received will submit this information electronically, and intends to leverage existing IT systems for the collection of this information. HHS foresees that participating issuers and third party administrators will attest that the information collection is correct and HHS intends to have the capability to accept electronic signatures for this purpose.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

Small businesses are not affected by this collection.

6. Less Frequent Collection

If applicable participating issuers and third party administrators do not provide this information collection annually, the participating issuers would not receive a user fee adjustment in a timely manner, and participating issuers and third-party administrators that make payments for contraceptive services under this accommodation would not be reimbursed for the cost of these services in a timely manner.

7. Special Circumstances

HHS requires third party administrators and participating issuers to maintain certain records with respect to the user fee adjustment for a period of ten years. Specifically, third party administrators would be required to maintain (i) a copy of the self-certification provided by the eligible organization for each self-insured plan with respect to which a user fee adjustment is received, (ii) documentation demonstrating that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2), and (iii) documentation supporting the total dollar amount of the payments for contraceptive services submitted by the third party administrator. Additionally, participating issuers receiving an adjustment in the FFE user fee under this section for a particular calendar year must maintain documentation demonstrating that it timely paid each third party administrator, with respect to which it received such adjustment any amount required under paragraph 45 CFR 156.50(d)(5). This timeframe is consistent with the statute of limitations under the False Claims Act and standards used for other Exchange programs.

8. Federal Register/Outside Consultation

A Federal Register notice (78 FR 50060) was published on August 16, 2013 providing the public with 60 days to comment. HHS received one comment in response to this Federal Register notice. The commenter stated that the estimated burden does not take into account the costs third party administrators will incur in developing systems to support these aforementioned data submissions, and noted that it is not clear whether the third party administrator must file one report for each issuer arrangement or a single report for all arrangements. The burden associated with these requirements only accounts for the extraction and submission of the required data to HHS, as we anticipate that third party administrators will utilize existing systems for tracking costs associated with the contraceptive services.

As shown in the proposed instrument *Third Party Administrator Submission Form to Receive the Federally-facilitated Exchange User Fee Adjustment*, the third party administrator may submit one form for all issuer arrangements. The commenter also noted the *Proposed Data Elements for Third Party Administrators' Submission Requirements to Receive the Federally-facilitated Exchange User Fee Adjustment* requires third party administrators to include the name and registered Health Insurance Oversight System (HIOS) ID for each self-insured plans for which the self-certification is received but noted there may be many self-insured plans that do not have a HIOS ID. We are no longer requiring self-insured plans to provide a HIOS ID for this submission. Lastly, the commenter asked CMS to issue clarifying rules or guidance to address situations in which an issuer participating in the FFE is not available to participate in the user fee credit. We will consider how to address this situation in the future.

At the time of the publication of the 60-day Federal Register notice (78 FR 50060), CMS provided a list of proposed data elements (Appendix A). As stated earlier, the August 27, 2014 proposed rule would expand the definition of an eligible organization, which would result in a broader application of these proposed information collection requirements. Therefore, we proposed to revise the earlier proposed collection to account for the burden of these information collection requirements for the entities identified in the proposed rule. On September 29, 2014, HHS published a revised Federal Register notice (79 FR 58354) providing the public with 60 days to comment. HHS did not receive any comments that were focused on the information collection instruments or burden associated with the FFE user fee adjustment.

9. Payments/Gifts to Respondents

No payments and/or gift will be provided to respondents.

10. Confidentiality

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

11. Sensitive Questions

These information collections involve no sensitive questions.

12. Burden Estimates (Hours & Wages)

Average labor costs (including fringe benefits) used in the burden estimates are calculated using data available from the Bureau of Labor Statistics.

Self-Certification and Alternate Notification Process for Eligible Organizations

The July 2013 final regulations require an eligible organization that seeks an accommodation to self-certify that it meets the definition of an eligible organization using the EBSA Form 700 and to provide EBSA Form 700 directly to each third party administrator (TPA) or issuer under the plan that would otherwise arrange for or provide the covered contraceptive services. If adopted, the August 2014 proposed regulations would extend this notice requirement to for-profit eligible organizations, such that all entities that meet the definition of an eligible organization would either use the EBSA Form 700 method of self-certification or the alternative process to of providing notice to HHS. Based on recent litigation, HHS believes that approximately 71 for-profit eligible organizations that would now have the option to provide the alternative notice to HHS rather than self-certifying to their TPAs/issuers using the EBSA Form 700. For eligible organizations, submission of the alternate direct notice to HHS represents a direct information collection requirement, and submission of the EBSA Form 700 to issuers or TPAs represents a third-party information collection requirement imposed jointly by the Departments of Labor and Health and Human Services. The burden associated with this requirement is accounted for in the Supporting Statement for the August 2014 Interim Final rule (CMS-10535) and the Supporting Statement for the disclosures proposed in the NPRM published on August 22, 2014 (CMS-10459).

Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(d))

The July 2013 final regulations direct a health insurance issuer providing 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 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 with application materials distributed in connection with enrollment (or reenrollment) 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 provides separate payments for contraceptive services. To satisfy the notice requirement, issuers may use the model language set forth in the July 2013 final regulations or substantially similar language.

Based on the plaintiffs in recent litigation, HHS believes that approximately 813 eligible organizations (including for-profit and non-profit employers) would be subject to this information collection requirement if the proposed rule extends the accommodations set forth in the final regulations to both non-profit and for-profit eligible organizations. We estimate that each issuer would 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. For each notice sent by mail, an issuer would incur an additional cost of approximately $0.51 ($0.46 in postage and $0.05 for printing). Accounting for mailing costs, we assume that each

issuer will incur a cost of approximately $45 as a result of this notification requirement.

Although it is unknown how many issuers provide health insurance coverage in connection with insured plans of eligible organizations, we estimate that approximately 40 percent of eligible organizations provide health insurance in connection with insured plans, and that the remaining 60 percent of eligible organizations provide health insurance coverage through a self-insured group health plan. Therefore, of approximately 813 eligible organizations, we estimate that approximately 325 will provide health insurance coverage through an issuer, resulting in 325 issuers subject to this written notification requirement. At an estimated cost of $45 per issuer, we estimate an aggregate cost of approximately $14,625 as a result of this notification requirement.

Table 12.1 Estimated Annualized Burden for Notice of Availability of Separate Contraception Payments

Notice	Number of respondents	Number of responses	Total Estimated Annual Burden Hours	Total Estimated Annual Cost
Written Notice of Availability for Insured Plan Participants	325	325	325	$14,625

Notification of Intent Submitted by TPAs (§147.131(d))

The July 2013 final rule requires TPAs to submit to HHS a notification that the TPA intends for a participating issuer to seek an FFE user fee adjustment with respect to the TPA for payments for contraceptive services, by the later of January 1, 2014, or the 60th calendar day following the date on which the TPA receives a copy of a self-certification from an eligible organization.

As stated elsewhere in this supporting statement, we estimate that approximately 60 percent of eligible organizations provide health insurance coverage through a self-insured group health plan, and that all self-insured group health plans use the services of a TPA. Consequently, assuming each self-insured eligible organization uses one TPA, we estimate that approximately 488 TPAs would be subject to this notification requirement.

We estimate that each TPA would need approximately 30 minutes of insurance specialist work (at $38.49 per hour) which includes 5 minutes for recordkeeping, and 5 minutes of senior management review (at $112.43 per hour) to submit this notification to HHS, resulting in a cost of $28.61 per TPA. Therefore, for 488 TPAs, we assume an aggregate burden of approximately 244 hours and $6,981 associated with this requirement.

Table 12.2 Estimated Annualized Burden for Notification of Intent to Seek User Fee Adjustment

Notice	Number of respondents	Number of responses	Total Estimated Annual Burden Hours	Total Estimated Annual Cost
Notification of Intent submitted by TPAs	488	488	244	$6,981

Collections for FFE User Fee Adjustment (§156.50(d))

The final rule requires a participating issuer seeking an FFE user fee adjustment to submit to HHS, in the year following the calendar year in which the contraceptive services for which payments were made under the accommodation described previously were provided, the following information: (A) identifying information for the participating issuer and each third party administrator that received a copy of the self-certification with respect to which the participating issuer seeks an adjustment in the FFE user fee (whether or not the participating issuer was the entity that made the payments for contraceptive services); (B) identifying information for each self-insured group health plan with respect to which a copy of the self-certification was received by a third party administrator and with respect to which the participating issuer seeks an adjustment in the FFE user fee; and (C) for each such self-insured group health plan, the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year under the accommodation.

In prior rulemaking, HHS estimated that 475 issuers will participate in the FFE.[1] We believe that those third party administrators that also offer a QHP through the FFE are most likely to seek the user fee adjustment. However, we also recognize that not all of the 488 TPAs estimated above offer a QHP in the FFE. Based on the administrative complexities of entering into these arrangements, we anticipate that some QHP issuers will seek the adjustment on behalf of multiple independent third party administrators. Therefore, we assume that approximately 10 percent of QHP issuers that participate in the FFM (approximately 48 QHP issuers) will seek the adjustment.

We estimate that each issuer would need approximately 3 hours of senior actuarial work (at $200 per hour), 5 hours of insurance specialist (at $38.49 per hour, which includes 5 minutes for recordkeeping), 2 hours for legal counsel (at $83.10 per hour), and 1 hour for a senior executive (at $112.43 per hour) for a total estimate of $1,071 per participating issuer. Therefore, for 48 QHP issuers, we assume the aggregate burden associated with this requirement is approximately 528 hours, as an approximate cost of $51,412.

HHS intends to collect the required data elements for issuers to receive the FFE user fee adjustment through a Microsoft Excel spreadsheet. To facilitate submission of the required data elements in a spreadsheet format, HHS intends to make a spreadsheet of the required data elements available upon finalization of this PRA. We do not anticipate that submission of the

[1] Patient Protection and Affordable Care Act; Program Integrity: Exchange Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Parameters for 2014 Final Rule (78 FR 65046)

required data elements in a spreadsheet format will affect the burden estimate associated with the submission.

Table 12.3 Estimated Annualized Burden of Collection of User Fee Adjustment Information from FFE Participating Issuers

Notice	Number of respondents	Number of responses	Total Estimated Annual Burden Hours	Total Estimated Annual Cost
Collection of User Fee Adjustment Information from FFE Participating Issuers	48	48	528	$51,412

Notification Requirements for TPAs Receiving Payment under the Accommodation

The final rule requires the third party administrator to submit to HHS, in the year following the calendar year in which the contraceptive services for which payments were made under the accommodation described previously were provided, the following information: (A) identifying information for the third party administrator and the participating issuer; (B) identifying information for each self-insured group health plan with respect to which the participating issuer seeks an adjustment in the FFE user fee; (C) the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year; (D) for each self-insured group health plan with respect to which the third party administrator made payments for contraceptive services, the total dollar amount of such payments that were provided during the applicable calendar year under the accommodation described previously (if such payments were made by the participating issuer directly, the total dollar amount should reflect the amount reported to the third party administrator by the participating issuer; if the third party administrator made or arranged for such payments, the total dollar amount should reflect the amount of the payments made by or on behalf of the third party administrator); and (E) an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2).

CMS sought comment on the number of TPAs that intend for a participating issuer to seek such an adjustment for this purpose in the 60-day Federal Register Notice published on August 16, 2013 (78 FR 50060), but received no comments. Therefore, based on the calculations noted above, we estimate that 488 TPAs will be subject to this collection.

HHS estimated that each TPA would need approximately 5 hours of clerical labor (at $38.64 per hour, which includes 5 minutes for recordkeeping), 3 hours of senior actuarial work (at $200 per hour), 2 hours for legal counsel (at $83.10 per hour), and 1 hour for a senior executive (at $112.43 per hour), for a total estimate of $1,072 per TPA. Therefore, we assume the aggregate

burden associated with this requirement is approximately 5,368 hours, as an approximate cost of $523,035.

HHS intends to collect the required data elements for third-party administrators to receive the FFE user fee adjustment through a Microsoft Excel spreadsheet. To facilitate submission of the required data elements in a spreadsheet format, HHS intends to make a spreadsheet of the required data elements available upon finalization of this PRA. We do not anticipate that submission of the required data elements in a spreadsheet format will affect the burden estimate associated with the submission.

Table 12.4 Estimated Annualized Burden of Collection of User Fee Adjustment Information from Third Party Administrators

Notice	Number of respondents	Number of responses	Total Estimated Annual Burden Hours	Total Estimated Annual Cost
Collection of User Fee Adjustment Information from Third Party Administrators	488	488	5,368	$523,035

13. Capital Costs

Third party administrators and participating issuers are not expected to incur capital costs to fulfill these requirements. However, some large third party administrators may choose to build systems to automate this process to lower their costs.

14. Cost to the Federal Government

CMS staff is expected to review the notification of intent submitted by a third party administrator, and the user fee adjustment information submitted by participating issuers and third party administrators. CMS will also review the self-certification notice submitted by for-profit eligible organizations (for non-profit eligible organizations, the burden associated with this requirement is accounted for under CMS Form 10535). We anticipate that a reviewer (at an hourly wage of a Grade 12/Step 1 in the Washington, DC area) will need 80 hours to review the two information collections that apply to a total of 536 respondents (325 fully-insured issuers and 488 TPAs). We also estimate that an analyst (at an hourly wage of a Grade 13/Step 5 in the Washington, DC area) would need 80 hours to process information received from TPAs that are receiving payment under the accommodation (approximately 488 TPAs) and calculate and apply the user fee adjustment to the FFE user fee amount (for approximately 48 FFE issuers). This includes the time to review and approve the information submitted under this collection. Therefore, accounting for an additional 35 percent for fringe benefits and overhead, we estimate total Federal government costs of $9,187

as a result of this requirement.

Table 12.5 Estimated Costs to Federal Government

Type of Federal Employee Support	Total Burden Hours per Reviewer (hours)	Total Reviewers	Hourly Wage Rate (GS 12 and 13 equivalent) – (includes fringe)	Total Federal Government Costs
Review of Notifications of Intent	80	1	$49	$3,913,
Processing of User Fee Adjustment Information	80	1	$66	$5,274
Total	160	2		$9,187

15. Changes to Burden

This is a new data collection. HHS has not changed the burden estimate from what was previously estimated in the Federal Register Notice that was published for public comment on September 29, 2014 (79 FR 58354).

16. Publication/Tabulation Dates

We anticipate applying the FFE user fee adjustment on a monthly basis beginning at the end of the 2015 calendar year. As stated in the July 2, 2013 final rule, issuers will submit data for benefit year once annually in the year following the applicable benefit year. However, the July 15, 2015 deadline for submitting data for the user fee adjustment will not apply. For the initial collection of 2014 benefit year data, participating FFE issuers seeking the user fee adjustment should submit the spreadsheet with the required data elements to FFMuserfeeadjustments@cms.hhs.gov within 60 days of finalization of this PRA.

17. Expiration Date

Not applicable

18. Certification Statement

There is no exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.