A. <u>Background</u>

On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA; P.L. 111-148) was signed into law and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) was signed into law. The two laws implement various health insurance policies.

On June 19, 2013, HHS published proposed rule CMS-9957-P: *Program Integrity: Exchanges, SHOP, Premium Stabilization Programs, and Market Standards* (78 FR 37302) (Program Integrity Proposed Rule) which, among other things, contained third party disclosure requirements and data collections that supported the oversight of premium stabilization programs, State Exchanges, and qualified health plan (QHP) issuers in Federally- facilitated Exchanges (FFEs). Parts of the proposed rule were finalized as Patient Protection and Affordable Care Act; Program Integrity: Exchange, *Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule* (Program Integrity Final Rule II), 78 FR 25326 (October 24, 2013). This ICR relates to a portion of the information collection request (ICR) requirements set forth in the final rule.

B. Justification

1. <u>Need and Legal Basis</u>

The Program Integrity Final Rule II, 78 FR 25326, among other things, provides for the oversight of health insurance issuers to protect consumers and the financial integrity of the FFEs. The oversight includes ensuring compliance with Marketplace requirements, such as the maintenance of records requirement and by participation in investigations and compliance reviews. This ICR deals with the burdens on Issuers that undergo HHS compliance reviews pursuant to 156 C.F.R. 156.715(a), performed to ensure ongoing compliance with Exchange standards applicable to issuers offering QHPs in a FFE, consistent with the Program Integrity Final Rule II. It also details burdens related maintenance of records for HHS review under 156 C.F. R. 156.705, to enforcement remedies under 156 C.F.R. Subpart I for non-compliance with FFR standards, and to administrative review of enforcements sanctions under 156 C.F.R. Subpart J.

2. Information Users

The program integrity data collections and third-party disclosure requirements assist HHS in determining Exchange compliance with Federal standards and in monitoring QHP issuers in FFEs for compliance with Federal QHP issuer standards. The data collected by health insurance issuers and Exchanges inform HHS, Exchanges, and health insurance issuers as to the participation of individuals, employers, and employees in the individual Exchange, and in SHOP.

3. <u>Use of Information Technology</u>

The majority of the information that is required for this ICR is submitted electronically. HHS staff analyzes and reviews the data in the same manner by which they were was submitted and communicates with States, health insurance issuers, and other entities using e-mail, telephone, or other electronic means.

4. <u>Duplication of Efforts</u>

This information collection does not duplicate any other Federal effort.

5. <u>Small Businesses</u>

This information collection does not have a significant impact on small business.

6. <u>Less Frequent Collection</u>

Due to the required flow of information between multiple parties and flow of funds for payments for health insurance coverage within the Exchange, it is necessary to collect information according to the indicated frequencies. If the information is collected less frequently, the result would be less accurate, untimely or unavailable eligibility, enrollment or payment information for Exchanges, insurers, employers, and individuals. This would lead to delayed payments to insurers; late charges to or payments by employers and enrollees; the release of misleading information regarding health care coverage to potential enrollees; and an overall stress on the organizational structure of the Exchanges.

7. <u>Special Circumstances</u>

Maintenance of records requirements are found in 45 CFR 156.705, which requires States and QHP issuers in FFEs to maintain records for a time period of ten years. This time frame is necessary for HHS to be consistent with the statute of limitations under the False Claims Act and the record retention requirements set forth in 45 CFR 153.620(b).

Section 156.905 provides respondents with the right to request a hearing if the request complies with §156.907 within 30 days after the date of issuance of either HHS's notice of proposed assessment under §156.805, notice of decertification of a QHP under §156.810(c) or §156.810(d). The timeline is necessary to provide entities with the protections provided by the Administrative Procedure Act, 5 U.S.C. 554 and 556.

8. Federal Register/Outside Consultation

HHS consulted with stakeholder regarding the requirements in this information collection, and based many of the requirements in this information collection on those consultations. HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange grant process, and meetings with other stakeholders including consumer advocates, employers, agents, brokers, and other interested parties.

A 60-day Notice was published in the Federal Register on April 9, 2021 (86 FR 18534). No comments were received. A 30-day Notice will be published in the Federal Register on XXXXX (86 FR XXXXX) for the public to submit written comment on the information collection requirements.

9. <u>Payments/Gifts to Respondents</u>

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

10. <u>Confidentiality</u>

To the extent of the applicable law and HHS policies, HHS maintains respondent privacy with respect to the information collected.

11. <u>Sensitive Questions</u>

There are no sensitive questions included in this information collection effort.

12. <u>Burden Estimates (Hours & Wages)</u>

Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the May 2019 National Industry-Specific Occupational Employment and Wage Estimates (Bureau of Labor Statistics (BLS) (<u>May 2019 National Occupational Employment</u> and <u>Wage Estimates</u>).

OES Designation	Occupational Code	Mean Hourly Wage (\$/hour)	Fringe Benefits and Overhead (\$/hour)	Adjusted Hourly Wage (\$/hour)
Actuary	15-2011	\$58.16	\$58.16	\$116.32
Network Administrator	15-1244	\$42.51	\$42.51	\$85.02
Compliance Officer	13-1041	\$35.03	\$35.03	\$70.06
General and Operations (Senior) Manager	11-1021	\$59.15	\$59.15	\$118.30
Health Policy Analyst	15-2031	\$43.56	\$43.56	\$87.12
Attorney	23-1011	\$69.86	\$69.86	\$139.72

Table 1: Adjusted Hourly Wages Used in Burden Estimates

The following sections of this document contain estimates of burden imposed by the associated information collection requirements; however, not all of these estimates are subject to the data collection requirements under the PRA for the reasons noted.

Change of Ownership (§156.330)

§156.330 requires the QHP issuer to notify HHS and provide the legal name and tax identification number of the new owner of the QHP and the effective date of the change of ownership to HHS within 30 days of the effective date. We estimate fewer than 10 QHP issuers will report changes of ownership. While this reporting requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(c)(4) and 44 USC 3502(3)(A)(i), since fewer than 10 entities would be affected. Therefore, we are not seeking approval from OMB for these information collection requirements.

Oversight and Standards for Issuers of Qualified Health Plans in the Federally-facilitated Exchange (§156.705 to §156.715)

The burden estimates for §§156.705 and 156.715 reflect that the FFEs include 361 QHP issuers. We update the number of issuers in the FFEs from the original estimated number to reflect more current information on the number of issuers expected to participate in the FFEs. The burden estimate is based on HHS estimates of the labor costs related to maintaining these records; issuers already have the records associated with this provision. Additionally, HHS does not specify the technology issuers choose to use to maintain these records. Therefore, HHS will not provide issuers with a standardized collection instrument for issuers to submit this information.

Section 156.705 provides that issuers offering QHPs in an FFE must maintain all documents and records (whether paper, electronic or other media), and other evidence of accounting procedures and practices necessary for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs.

Such activities include: (1) periodic auditing of the QHP issuer's financial records, including data related to the QHP issuer's ability to bear the risk of potential financial losses; and (2) compliance reviews and other monitoring of a QHP issuer's compliance with all Exchange standards applicable to issuers offering QHPs in the FFEs listed in part 156. The burden includes utilizing existing technology and systems to process and maintain this information. This reflects 60 hours of work by an actuary (at \$116.32 an hour), 15 hours by a network administrator (at \$85.02 an hour), 15 hours by a compliance officer (at \$70.06 an hour), and 10 hours for a senior manager to review (at \$118.30 an hour). We estimate that it will take 100 hours total at a cost of \$10,488.40 for a QHP issuer to maintain these records for an aggregate burden of 36,100 hours and \$3,786,312.40 for all 361 QHP issuers.

Pursuant to 45 C.F.R. §§156.705 and 156.715, QHP issuers must maintain records for HHS review. The table below displays the burden for issuers relating to the regulatory provision.

Labor	Number of	Hourly Labor Costs	Burden	Total Burden	Total Burden
Category	Respondents		Hours	Costs (per	Costs (All
		Fringe benefits)		Respondent)	Respondents)
Actuary	361	\$116.32	60	\$6,979.20	\$2,519,491.20
Network	361	\$85.02	15	\$1,275.30	\$460,383.30
Administrator					
Compliance	361	\$70.06	15	\$1,050.90	\$379,374.90
Officer					
Senior	361	\$118.30	10	\$1,183.00	\$427,063.00
Manager					
Total			100	\$10,488.40	\$3,786,312.40

Table 2: Burden to QHP	Issuers to Maintain Records
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Section 156.705(d) provides that QHP issuers must make all records described in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request. In estimating the annual hour and cost burden on QHP issuers of making these records available to such authorities upon request, we assumed that such requests would normally be made in connection with a formal audit or compliance review or a similar process. Our burden estimates for this section address the hour and cost burden of making records available to HHS, the OIG, the Comptroller General, or their designees, for audit. Our estimates reflect our assumptions that about 21 QHP issuers would be subject to a formal audit in a given year and that the burden on issuers of making the records available would include the time, effort, and associated cost of compiling the information, reviewing it for completeness, submitting it to the auditor(s), and participating in telephone or in-person interviews. We anticipate using a risk-based approach to selection of the majority of QHP issuers for compliance review so that burdens to the issuer community would generally be linked to the QHP issuers' risk. This reflects 75 hours of work by an actuary (at \$116.32 an hour), 10 hours by a compliance officer (at \$70.06 an hour), and 5 hours for a senior manager to

review (at \$118.30 an hour). We estimate it will take 90 hours at a cost of \$10,016.10 for an issuer to make its records available for an audit for a total of 2,700 hours and \$300,483.00 across all QHP issuers subject to this requirement, which we estimate at an upper end as 30 issuers. Pursuant to 45 C.F.R. §156.705(d), QHP issuers must make records available to HHS, the OIG, the Comptroller General, or their designees for audit. The table below displays the burden for issuers relating to the regulatory provision.

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (per Respondent)	Total Burden Costs (All Respondents)
Actuary	30	\$116.32	75	\$8,724.00	\$261,720.00
Compliance Officer	30	\$70.06	10	\$700.60	\$21,018.00
Senior Manager	30	\$118.30	5	\$591.50	\$17,745.00
Total			90	\$10,016.10	\$300,483.00

Table 3: Burden to QHP Issuers to Make Records Available for Audit

Section 156.715 establishes the general standard that QHP issuers are subject to compliance reviews. Our burden estimates for §156.715 address the estimated annual hour and cost burden on QHP issuers of complying with the records disclosure requirements associated with compliance reviews conducted by an FFE. We assume that HHS will conduct desk reviews of 18 QHP issuers each year. For each QHP issuer desk review we estimate an average of 40 hours of administrative work to assemble the requested information by a health policy analyst (at \$87.12 an hour), 19.5 hours to review the information for completeness and an additional 30 minutes for a compliance officer to submit the information to HHS (at \$70.06 an hour). There will also be an additional 10 hours to spend on phone interviews conducted by the compliance reviewer and 2 hours to spend speaking through processes with the compliance reviewer (at \$70.06 an hour). We estimate it will take 72 hours at a cost of \$5,726.72 for an issuer to make information available to HHS for a desk review for a total of 1,296 hours and \$103,080.96 across all issuers that may be subject to this information collection requirement.

Pursuant to 45 C.F.R. §156.715, QHP issuers must make information available to HHS for compliance review. The table below displays the burden for issuers relating to the regulatory provision.

Table 4: Burden to QHP Issuers to Provide Information for Compliance Review

Labor	Number of	Hourly Labor Costs	Burden	Total Burden	Total Burden
Category	Respondents	(Hourly rate + 100%	Hours	Costs (per	Costs (All
		Fringe benefits)		Respondent)	Respondents)
Health Policy	18	\$87.12	40	\$3,484.80	\$62,726.40
Analyst					
Compliance	18	\$70.06	32	\$2,241.92	\$40,354.56
Officer					
Total			72	\$5,726.72	\$103,080.96

We assume that HHS will conduct onsite reviews of 3 QHP issuers each year. For each onsite review we estimate it will take an average of 40 hours for a health policy analyst (at \$87.12 an hour) to assemble the requested information, and 19.5 hours for a compliance officer (at \$70.06 an hour) to review the information for completeness and 30 minutes to submit the information to HHS in preparation for an onsite review. An onsite review requires an additional 2 hours to schedule the onsite activities with the compliance officer (at \$70.06 an hour), 4 hours for introductory meeting, 8 hours to tour reviewers onsite, 10 hours of interview time, 2 hours to walk through processes with the reviewer, and 4 hours for concluding meetings. This is a total of approximately 60 hours of preparation time and an additional 30 hours for onsite time for each QHP. We estimate it will take 90 hours at a cost of \$6,987.80 for an issuer to make information available to HHS for an onsite review. We estimate that the burden for all respondents that may be subject to this information collection will be 270 hours at a cost of \$20,963.40

Pursuant to 45 C.F.R. §156.715, QHP issuers must make information available to HHS for onsite review. The table below displays the burden for issuers relating to the regulatory provision.

Labor	Number of	Hourly Labor Costs	Burden	Total Burden	Total Burden
Category	Respondents	(Hourly rate + 100%	Hours	Costs (per	Costs (All
		Fringe benefits)		Respondent)	Respondents)
Health Policy	3	\$87.12	40	\$3,484.80	\$10,454.40
Analyst					
Compliance	3	\$70.06	50	\$3,503.00	\$10,509.00
Officer					
Total			90	\$6,987.80	\$20,963.40

 Table 5: Burden to QHP Issuers to Provide Information for Onsite Review

HHS may require further information or clarification after reviewing the information provided by the issuer under 45 C.F.R. §156.715. The table below displays the burden for issuers for providing clarifying information under the regulatory provision. We estimate it will take 2 hours at a cost of \$140.12 for an issuer to provide further information or clarification to HHS. We estimate that the burden for all respondents that may be subject to this information collection will be 30 hours at a cost of \$2,101.80.

Table 6: Burden to QHP Issuers in Cases in which HHS Requires Clarification

Labor	Number of	Hourly Labor Costs	Burden	Total Burden	Total Burden
Category	Respondents	(Hourly rate + 100%)	Hours	Costs (per	Costs (All
		Fringe benefits)		Respondent)	Respondents)
Compliance	15	\$70.06	2	\$140.12	\$2,101.80
Officer					
Total			2	\$140.12	\$2,101.80

Administrative Review of QHP Issuer Sanctions in a Federally-facilitated Exchange (§156.901 to §156.963)

We base our burden estimate on the assumptions that one issuer will be subject to a CMP and that one issuer will have a QHP that it offers in an FFE decertified. We assume that the issuer in each case will choose to exercise its right to a hearing and will submit a valid request for hearing. The hours involved in preparing this request may vary; for the purpose of this burden estimate we estimate an average of 24 hours will be needed: 10 hours for the compliance officer to gather and assemble the necessary background materials described under §156.907, and prepare the written request (at \$70.06 an hour), 12 hours for an attorney (at \$139.72 an hour) to review the background materials and written request and provide recommendations to the senior manager, and 2 hours for the senior manager (at \$118.30 an hour) to discuss and act upon the attorney's recommendations and submit the written request. We estimate that it will take a total of 24 hours at a cost of \$2,613.84 for an issuer to prepare and submit a request for a hearing. This estimate includes any statement of good cause under §156.805(e)(3) or request for extension under §156.905(b), if applicable.

Pursuant to 45 C.F.R. §156.907, a QHP issuer submitting a request for hearing must gather and assemble necessary background materials. In addition, an issuer may submit statement of good cause under §156.805(e)(3) or request for extension under §156.905(b). The table below displays the burden for issuers relating to the regulatory provision.

Labor	Number of	Hourly Labor Costs	Burden	Total Burden	Total Burden
Category	Respondents	(Hourly rate + 100%	Hours	Costs (per	Costs (All
		Fringe benefits)		Respondent)	Respondents)
Compliance	1	\$70.06	10	\$700.60	\$700.60
Officer					
Attorney	1	\$139.72	12	\$1,676.64	\$1,676.64
Senior Manager	1	\$118.30	2	\$236.60	\$236.60
Total			24	\$2,613.84	\$2,613.84

 Table 7: Burden to a QHP Issuer to Submit a Request for Hearing

The aggregate annual cost across all respondents is \$4,215,555.40. The table below provides a summary of the estimates within this package.

Table 8: Summary of Total Burden

Table Number: Name	C.F.R. Section	Burden Hours	Burden Cost
Table 2: Burden to QHP Issuers to Maintain Records	45 C.F.R. §§156.705 and 156.715	36,100	\$3,786,312.40
Table 3: Burden to QHP Issuers to Make Records Available for Audit	45 C.F.R. §156.705(d)	2,700	\$300,483.00
Table 4: Burden to QHP Issuers to Provide Information for Compliance Review	45 C.F.R. §156.715	1,296	\$103,080.96
Table 5: Burden to QHP Issuers toProvide Information for Onsite Review	45 C.F.R. §156.715	270	\$20,963.40
Table 6: Burden to QHP Issuers in Cases in which HHS Requires Clarification	45 C.F.R. §156.715	30	\$2,101.80
Table 7: Burden to a QHP Issuer to Submit a Request for Hearing	45 C.F.R. §156.907, §156.805(e)(3), and §156.905(b)	24	\$2,613.84
Total		40,420	\$4,215,555.40

13. <u>Capital Costs</u>

There are no capital costs associated with these information collections.

14. <u>Cost to Federal Government</u>

The burden to the Federal government for maintaining the systems and policies associated with this information collection is \$292,782.00. The calculations for HHS employees' hourly salary was obtained from the OPM website: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/GS https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/GS https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/GS https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/GS https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/GS https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/GS <a href="https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salarie

Table 9: Administrative Burden Costs for the Federal Government Associated with theProgram Integrity NPRM

Task	Estimated Cost			
Program Integrity Information Collections				
2GS-13: 2 x \$81.24 x 1,500 hours	\$243,720.00			
Technical Assistance to States				
2GS-13: 2 x \$81.24 x 100 hours	\$16,248.00			
Managerial Review and Oversight				
2 GS-15: 2 x \$109.38 x 150 hours	\$32,814.00			
Total Costs to Government	\$292,782.00			

15. <u>Changes to Burden</u>

The estimated burden hours for this data collection is currently approved for 48,732 hours. With this ICR, the annualized burden hours is approximately 40,420 hours. This is a reduction of 8,312 burden hours compared to the previously approved clearance. The reduction in burden for this data collection

request is due to the fact that fewer QHP issuers must to respond to the data collection.

16. <u>Publication/Tabulation Dates</u>

Results of the collection will not be made public.

17. Expiration Date

There are no instruments associated with this data collection.