

**Supporting Statement for
Program Integrity II
(CMS-10516/OMB Control Number 0938-1277)**

A. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, “Affordable Care Act”), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), also called Marketplaces, including the Small Business Health Options Program (SHOP). The Exchanges, for which enrollment was operational by October 1, 2013 and coverage became effective as early as January 1, 2014, enhances competition in the health insurance market, expands access to affordable health insurance for millions of Americans, and provides consumers with a place to easily compare and shop for health insurance coverage.

On June 19, 2013, HHS published the proposed rule CMS-9957-P: *Program Integrity: Exchanges, SHOP, Premium Stabilization Programs, and Market Standards* (78 FR 37302) (Program Integrity Proposed Rule). Among other things, the Program Integrity Proposed Rule sets forth financial integrity provisions and protections against fraud and abuse. The third party disclosure requirements and data collections proposed in the Program Integrity Proposed Rule support the oversight of premium stabilization programs (transitional reinsurance, risk corridors and risk adjustments), State Exchanges, and qualified health plan (QHP) issuers in Federally- facilitated Exchanges (FEEs). HHS finalized some provisions from the Program Integrity Proposed Rule in a final rule, *Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals*, published on August 30, 2013. HHS displayed the final rule that finalized the remaining provisions from the Program Integrity Proposed Rule, CMS-9957-F2; CMS-9964-F3: *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* (Program Integrity Final Rule II) on October 24, 2013.

The original approved ICR affiliated with this final rule (OMB control number: 0938-1277) was titled *Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule II* and was approved on 8/26/2015. This Information Collection Request (ICR) serves as the formal request for renewal of the clearance. This ICR includes some of the information collection requirements from the previously approved final rule. The other ICRs from the original final rule are not included in this request will be submitted for OMB approval under separate collections.

B. Justification

1. Need and Legal Basis

Section 1311(c)(4) of the Affordable Care Act directs the Secretary of Health and Human Services (Secretary) to establish an enrollee satisfaction survey system that would evaluate the level of enrollee satisfaction of members in each QHP offered through an Exchange with more than 500 enrollees in the previous year.

Section 1321(a) of the Affordable Care Act provides general authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs, and other components of Title I of the Affordable Care Act.

Section 1321(c)(1) of the Affordable Care Act requires the Secretary to establish and operate an FFE within States that either: do not elect to operate an Exchange; or, as determined by the Secretary, will not have any required Exchange operational by January 1, 2014.

Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to enforce the Exchange standards using civil money penalties (CMPs) on the same basis as detailed in section 2723(b) of the Public Health Service Act (PHS Act). Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group market reforms contained in Title XXVII, Part A of the PHS Act when a State fails to substantially enforce these provisions.

Section 1311(e)(1)(B) of the Affordable Care Act specifies that an Exchange may certify a health plan as a QHP if the Exchange determines that making available such a health plan is in the interests of qualified individuals and qualified employers in the State or States in which the Exchange operates.

Section 1313 of the Affordable Care Act, combined with section 1321 of the Affordable Care Act, provides the Secretary with the authority to oversee the financial integrity, compliance with HHS standards, and efficient and non-discriminatory administration of State Exchange activities. Section 1313(a)(6)(A) of the Affordable Care Act specifies that payments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. 3729, et seq.) if those payments include any Federal funds.

The Program Integrity Final Rule II contains provisions that mandate third-party disclosure and data collections necessary to protect Federal funds and ensure that States Exchanges, premium stabilization programs, and QHP issuers in FFEs are in compliance with the Affordable Care Act. These information collection requirements are proposed for 45 CFR Parts 153, 155, and 156.

2. Information Users

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

3. Use of Information Technology

HHS anticipates that a majority of the systems, notices, and information collection required by this rule will be automated. A majority of the information that is required by the collection of information for this rule will be submitted electronically. HHS staff will analyze or review the data in the same manner by which it was submitted and communicate with States, health insurance issuers, and other entities using e-mail, telephone, or other electronic means.

HHS will be leveraging existing IT systems for the collection of the State specific data set forth in the information collection requirements in 45 CFR 156.135. HHS aims to lessen the burden on states for the required submission by using existing IT systems.

4. Duplication of Efforts

This information collection does not duplicate any other Federal effort.

5. Small Businesses

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

6. Less Frequent Collection

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. Special Circumstances

HHS proposes maintenance of records requirements in 156.705. HHS is proposing to require 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).

In proposed §156.905, HHS proposes to provide respondents with the right to request a hearing if the request complies with proposed §156.907 within 30 days after the date of issuance of either HHS' notice of proposed assessment under proposed §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 has consulted with stakeholders on many of the requirements in this information collection, and has 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 will be published in the Federal Register on XX/XX/2018 for the public to submit written comment on the information collection requirements.

9. Payments/Gifts to Respondents

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

10. Confidentiality

To the extent of the applicable law and HHS policies, HHS will maintain respondent privacy with respect to the information collected. Nothing in the information collection should be interpreted as preventing a State from being allowed to disclose its own data.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

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. Salaries for the positions cited were mainly taken from the Bureau of Labor Statistics (BLS) Web site (http://www.bls.gov/oco/ooh_index.htm).

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 the assumption that the FFEs will include 428 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 \$96.74 an hour), 15 hours by a network administrator (at \$81.68 an hour), 15 hours by a compliance officer (at \$67.54 an hour), and 10 hours for a senior manager to review (at \$117.08 an hour). We estimate that it will take 100 hours total at a cost of \$9,213.50 for a QHP issuer to maintain these records for an aggregate burden of 42,800 hours and \$3,943,378 for all 428 QHP issuers.

Table A

Labor Category	Number of Employees	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs	Total Burden Costs (All Respondents)
Actuary	1	\$96.74	60	\$5,804.40	
Network Administrator	1	\$81.68	15	\$1,225.20	
Compliance Officer	1	\$67.54	15	\$1,013.10	
Senior Manager	1	\$117.08	10	\$1,170.80	
Total (based on all 428 QHP issuers)			100	\$9,213.50	\$3,943,378

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 30 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 \$96.74 an hour), 10 hours by a compliance officer (at \$67.54 an hour), and 5 hours for a senior manager to review (at \$117.08 an hour). We estimate it will take 90 hours at a cost of \$8,516.30 for an issuer to make its records available for an audit for a total of 3,600 hours and \$340,652 across all QHP issuers subject to this requirement, which we estimate at an upper end as 40 issuers.

Table B

Labor Category	Number of Employees	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs	Total Burden Costs (All Respondents)
Actuary	1	\$96.74	75	\$7,255.50	
Compliance Officer	1	\$67.54	10	\$675.40	
Senior Manager	1	\$117.08	5	\$585.40	
Total (based on 40 issuers)			90	\$8,516.30	\$340,652

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 24 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 \$73.10 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 \$67.54 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 \$67.54 an hour). We estimate it will take 72 hours at a cost of \$5,085.28 for an issuer to make information available to HHS for a desk review for a total of 1,728 hours and \$122,047 across all issuers that may be subject to this information collection requirement.

Table C

Labor Category	Number of Employees	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs	Total Burden Costs (All Respondents)
Health Policy Analyst	1	\$73.10	40	\$2,924	
Compliance Officer	1	\$67.54	32	\$2,161.28	
Total (based on conducting desk reviews of 24 QHP issuers each year)			72	\$5,085.28	\$122,047

We assume that HHS will conduct onsite reviews of 6 QHP issuers each year. For each onsite review we estimate it will take an average of 40 hours for a health policy analyst (at \$73.10 an hour) to assemble the requested information, and 19.5 hours for a compliance officer (at \$67.54 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 \$67.54 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 \$6,301 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 540 hours at a cost of \$37,806.

Table D

Labor Category	Number of Employees	Hourly Labor Costs (Hourly rate + 100% Fringe	Burden Hours	Total Burden Costs	Total Burden Costs (All Respondents)
Health Policy Analyst	1	\$73.10	40	\$2,924	
Compliance Officer	1	\$67.54	50	\$3,377	
Total (based on conducting onsite reviews of 6 QHP issuers each year)			90	\$6,301	\$37,806

Table E

In cases in which HHS could potentially require clarification	Number of Employees	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs	Total Burden Costs (All Respondents)
Compliance Officer	1	\$67.54	2	\$135.08	
Total (based on 20 QHP issuers each year)			40	\$135.08	\$2,702

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 \$67.54 an hour), 12 hours for an attorney (at \$113.62 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 \$117.08 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 \$2,273 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.

Table F

Labor Category	Number of Employees	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs	Total Burden Costs (All Respondents)
Compliance Officer	1	\$67.54	10	\$675.40	
Attorney	1	\$113.62	12	\$1,363.44	
Senior Manager	1	\$117.08	2	\$234.16	
Total (based on one issuer will be subject to a CMP)			24	\$2,273	\$2,273

13. Capital Costs

There are no anticipated capital costs associated with these information collections.

14. Cost to Federal Government

The initial burden to the Federal government for the establishing the systems and policies associated with this information collection is \$278,590. The calculations for CCIIO 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_h.pdf

Table 1 - Administrative Burden Costs for the Federal Government Associated with the Program

Integrity NPRM

<u>Task</u>	<u>Estimated Cost</u>
Program Integrity Information Collections	
2GS-13: 2 x \$77.30 x 1,500 hours	\$231,900
Technical Assistance to States	
2GS-13: 2 x \$77.30 x 100 hours	\$15,460
Managerial Review and Oversight	
2 GS-15: 2 x \$104.10 x 150 hours	\$31,230
Total Costs to Government	\$278,590

15. Changes to Burden

The estimated burden hours for this data collection is currently approved for 383,122 hours. With this ICR, the annualized burden hours is approximately 48,732 hours. This is a reduction of 334,390 burden hours compared to the previously approved clearance. The reduction in burden for this data collection request is due to the fact that this is a continuation of information collection activities and there is no need for the initial burden that was included in the original approved package. Also, some of the ICRs in the original ICR have been removed.

16. Publication/Tabulation Dates

Results of the collection will not be made public.

17. Expiration Date

There are no instruments associated with this data collection.