Supporting Statement for Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act (CMS-10430/OMB Control Number: 0938-0702)

A. Background

Sections 2723 and 2761 of the Public Health Service Act (PHS Act) direct the Centers for Medicare and Medicaid Services (CMS) to enforce a provision (or provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 144, 146, 147, and 148 of title 45 of the Code of Federal Regulations) with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the group and individual market reforms, or when CMS has determined that a state is not substantially enforcing one or more of those provisions.

Section 2723 of the PHS Act directs CMS to enforce an applicable provision (or applicable provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 146 and 147 of title 45 of the Code of Federal Regulations) with respect to group health plans that are non-Federal governmental plans.

1. Market Reform Provisions under Title XXVII of the PHS Act

Title XXVII of the PHS Act includes provisions regarding the individual and group health insurance markets, and non-Federal governmental group health plans. These provisions are designed to make it easier for people to access health coverage and to reduce the limitations that can be placed on that coverage. The laws that amended title XXVII of the PHS Act are as follows:

- The Women's Health and Cancer Rights Act of 1998 (WHCRA), Public Law 105-277, title IX, was enacted on October 21, 1998. WHCRA requires group health plans and health insurance issuers that offer mastectomy coverage to also provide coverage for reconstructive surgery and certain other benefits in a manner determined in consultation with the attending physician and the patient.

- The Newborns' and Mothers' Health Protection Act of 1996 (NMHPA), Public Law 104-204, title VI, was enacted on September 26, 1996. NMHPA requires plans that provides hospital stays for childbirth to cover at least a 48-hour hospital stay following childbirth (96- hour stay in the case of a cesarean section).

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, was enacted on August 21, 1996. Title I of HIPAA requires group health plans and health insurance issuers to provide certain guarantees for availability and renewability of health coverage in the group and individual health insurance

markets.

- Michelle's Law, Public Law 110-381, was enacted on October 9, 2008. Michelle's Law addresses the situation in which loss of student status would cause a college student to lose dependent health coverage. It prevents issuers from terminating coverage if the loss of student status is a result of a medically necessary leave of absence for a serious illness or injury. The protection applies to an absence of up to twelve months.

- The Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110-233, was enacted on May 21, 2008. Title I of GINA prohibits discrimination in health coverage based on genetic information by group health plans, health insurance issuers in the group and individual markets, and issuers of Medicare supplemental (Medigap) policies.

- The Patient Protection and Affordable Care Act, Public Law 111-148, was enacted on March 23, 2010; and the Health Care and Education Reconciliation Act of 2010, Public Law 111-152, was enacted on March 30, 2010 (collectively known as the "Affordable Care Act"). The Affordable Care Act reorganizes, amends, and adds to the provisions of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets.

- The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), Public Law 110-343, division C, title V, subtitle B, was enacted on October 3, 2008. MHPAEA generally prohibits certain large group health plans and large group health insurance issuers from imposing financial requirements and treatment limitations on mental health or substance use disorder benefits that are more restrictive than the predominant requirements or limitations applied to substantially all medical/surgical benefits. MHPAEA was amended by the Affordable Care Act to also apply to health insurance issuers in the individual market. Through the Affordable Care Act's essential health benefits provision, MHPAEA also applies to small group health insurance coverage.

- The Expatriate Health Coverage Clarification Act of 2014 (EHCCA) was enacted on December 16, 2014 as part of the Consolidated and Further Continuing Appropriations Act, 2015, Division M, Public Law 113-235. The EHCCA provides that the market reform requirements of the Affordable Care Act generally do not apply to expatriate health plans, expatriate health insurance issuers with respect to expatriate health plans, and employers in their capacity as plan sponsors of expatriate health plans. However, the plans, coverage, sponsors and issuers must still satisfy the provisions of the PHS Act that would otherwise apply if not for the enactment of the Affordable Care Act. The EHCCA exception from the market reform requirements applies to expatriate health plans that are issued or renewed on or after July 1, 2015.

In addition, due to CMS' interpretation of the term "State" for purposes of the amendments to the PHS Act made by the Affordable Care Act, issuers in the U.S. territories are not subject to the group or individual market reforms under title XXVII of the PHS Act that were enacted in the Affordable Care Act. They must continue to comply with title XXVII provisions that would otherwise apply if not for enactment of the Affordable Care Act. They will also need to ensure that coverage offered to both private sector and public sector employer group health plans in the territories (which remain subject to the Affordable Care Act) comply with the group market reforms in the PHS Act as amended by the Affordable Care Act and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code.[1]

The statutory provisions and implementing regulations that are the subject of this submission implement group and individual market reforms under title XXVII of the PHS Act ("the group and individual market reforms"), as they apply to non-Federal governmental group health plans and group and individual health insurance issuers. The group provisions apply to employment related group health plans and to the issuers that sell insurance in connection with group health plans. For purposes of title XXVII of the PHS Act, all other health insurance is sold in the individual market.[2]

2. Enforcement Authority under Title XXVII of the PHS Act

Pursuant to sections 2723 and 2761 of the PHS Act (42 USC §§ 300gg–22 and 300gg–61), states are empowered to enforce the group and individual market reforms applicable to health insurance issuers under title XXVII of the PHS Act. Sections 2723(a)(2) and 2761(a)(2) of the PHS Act provide that, when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the group and individual market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions, CMS shall enforce such provision (or provisions) in the state.

The Federal regulations implementing sections 2723 and 2761 of the PHS Act are codified at 45 CFR 150.203. These regulations provide two possibilities for direct enforcement by CMS. The first is a situation in which a state notifies CMS that it does not have authority to enforce or is otherwise not enforcing the group and individual market reforms. This may include circumstances in which the state voluntarily invites CMS to enforce such Federal provisions directly. The second situation involves CMS' rendering of a formal determination, in accordance with Federal regulations, that a state lacks authority to enforce

[1] See e.g., Letter to Gary R. Francis, Commissioner, Office of Lieutenant Governor, Virgin Islands, dated July 16, 2014, available at https://www.cms.gov/CCIIO/Resources/Letters/Downloads/letter-to-Francis.pdf.

[2] Under title XXVII of the PHS Act, "individual market coverage" is any health insurance coverage that is not offered in connection with a group health plan. For the application of individual and group market requirements under title XXVII of the PHS Act when insurance coverage is sold to, or through, associations, see Insurance Standards Bulletin Series—INFORMATION issued on September 1, 2011.

or has failed to substantially enforce one or more provisions of the group and individual market reforms. In either situation, CMS may, and has a policy to seek to, accomplish its direct enforcement of the group and individual market reforms through a collaborative approach with the relevant state.

Pursuant to section 2723 of the PHS Act (42 USC §§ 300gg–22), CMS enforces an applicable provision (or applicable provisions) of title XXVII of the PHS Act with respect to group health plans that are non-Federal governmental plans.

The Federal regulations implementing section 2723 of the PHS Act are codified at 45 CFR 150.101 et seq. Section 2723(b)(1)(B) of the PHS Act provides CMS primary enforcement authority with respect to group health plans that are non-Federal governmental plans. The provisions of title XXVII of the PHS Act that apply to group health plans that are non-Federal governmental plans are enforced by CMS using the procedures in section 150.301 et. seq. The procedures set out in section 150.301 include, but are not limited to, CMS' authority to levy a civil money penalty on any non-Federal governmental plan (or employer that sponsors a non-Federal governmental plan) for failure to comply with PHS Act requirements, and initiating an investigation due to receipt of information that indicates that any non-Federal governmental plan that is a group health plan as defined in section 2791(a)(1) of the PHS Act and 45 CFR 144.103 may be failing to meet an applicable HIPAA requirement.

3. Form Filing Collection

Federal enforcement of title XXVII of the PHS Act, if necessary, in a state may include the collection and review of form filings from health insurance issuers. The collection of form filings is similar to state law requirements, and most state insurance departments require issuers to submit form filings. Generally, form filings are readily available and disclosed by health insurance issuers as part of their current operations under state law. States generally require health insurance issuers to submit form filings (for insurance products offered in the state) to the state for review for compliance with state law. If CMS should need to assume direct enforcement responsibility in a state, and the state already requires issuers in the state to submit form filings, the collection of form filings by CMS is exempt from the PRA because it does not meet the definition of a collection of information, as outlined in 5 CFR 1320.3(b)(3). In addition, Federal enforcement of provisions under title XXVII of the PHS Act, in some instances, will be implemented on a complaint basis or through a focused audit/investigation process, which is also exempt from the PRA as provided for in 5 CFR 1320.4(a)(2). This submission covers those limited instances where a state does not require issuers to submit form filings in some or all markets and CMS must enforce in that state for compliance with title XXVII of the PHS Act. As previously mentioned, in states where issuers are required to submit form filings, this collection will be exempt from the PRA. However, CMS is submitting this PRA to cover information collection requirements (ICRs) that may fall outside of the narrow exemptions, as well as for transparency.

4. Self-Funded Non-Federal Governmental Plans Opt-Out Provisions

Under section 2722(a)(2) of the PHS Act, a self-funded non-Federal governmental plan can elect to opt out of a limited number of title XXVII requirements. This submission covers the ICR related to notice to CMS of self-funded non-Federal governmental plan opt-out and notice to self-funded non-Federal governmental plan enrollees of the plan's election to opt out of these requirements.

5. State Engagement Coordination and Compliance Monitoring

CMS established the State Engagement Coordination (SEC) Team as an effective way to help assure the continuity of CMS' collaborative work with states. The SEC Team supports states in ensuring compliance with and enforcement of title XXVII of the PHS Act. The SEC Team provides technical assistance to states, answers state questions, and shares updates about new CMS regulations and guidance. Also, the SEC Team gathers information from the states by phone conversations, email requests, or other appropriate means related to issues such as but not limited to issuers' offerings in response to extensions of the transitional policy, new or revised rules about short-term, limited-duration insurance policies, and other matters that affect states' health insurance markets. This submission covers instances when the SEC Team needs to request information from the states in order to monitor the health insurance markets around the country as critical issues arise.

B. Justification

1 . Need and Legal Basis

A. ICRs relating to Group and Individual Market Reforms

This ICR associated with the group and individual market reforms will permit collections between the Federal government and states and health insurance issuers in varying compliance and enforcement situations ranging from cooperative Federal/state compliance and enforcement of group and individual market provisions to enforcement of selected provisions. This ICR also relates to Federal collection and review of health insurance issuers' form filings of group and individual market products in cases in which CMS assumes a direct enforcement role in a state that lacks authority to enforce or is not enforcing a provision (or provisions) in title XXVII of the PHS Act.

Sections 2723 and 2761 of the PHS Act support this ICR because CMS may need to collect and review state information to assess state authority, compliance and enforcement efforts related to provisions under title XXVII of the PHS Act. If CMS determines that a state lacks authority to enforce or is not substantially enforcing such provision (or provisions), CMS will need to collect a health insurance issuer's form filings for the group and individual market in that state in order to determine compliance with any group and individual market reform requirements under title XXVII of the PHS Act that the state is not substantially

enforcing. This collection will ensure compliance with provisions of title XXVII of the PHS Act. More importantly, this collection will help to ensure that consumers who are shopping for, or are enrolled in, private, individually purchased or employer-sponsored coverage or non-Federal governmental plans receive all of the consumer protections provided by the market reforms in the law.

Generally, form filings are readily available and disclosed by health insurance issuers as part of their current operations under state law. States generally review form filings to ensure compliance with state and Federal provisions. Form filing requirements vary from state to state; however, most include policy and application forms, endorsements, certificates, riders, amendments, and certifications. In states that are enforcing the requirements under title XXVII of the PHS Act, CMS does not need to review form filings. In states that are in a collaborative agreement with CMS to enforce the group and individual market reforms, states may continue to review form filings for compliance with Federal provisions. In states not assuming enforcement responsibilities in which CMS must enforce a provision (or provisions) of title XXVII of the PHS Act, CMS may collect the required information directly as part of its enforcement activities. This chart identifies the various documents that CMS may need to review in order to determine compliance with the group and individual market reforms in situations where CMS must enforce a provision (or provisions) of title XXVII of the PHS Act. The documents identified in the chart might not be collected in all cases. CMS will collect only the minimum information necessary to ensure compliance with the provision (or provisions) for which CMS must enforce.

Table 1: Issuer Form Filings for Review for Compliance in the Group and Individual Market

Requested Documents	Does the State Already Collect This Information on a Routine Basis?
Issuer name and e-mail address	Yes
Name, address, and telephone number where complaints are to be sent	Yes
Clear indication of the market for which the following materials are being submitted	Yes
Policy Forms and Contracts	Most States collect (Depends on State Authority)
Certificates/Outlines of Coverage	Depends on State Authority
Amendment Forms	Depends on State Authority
Policy Riders and Endorsements	Most States collect (Depends on State Authority)
Waivers or Opt-Out Provisions	Depends on State Authority
Advertising/Marketing Materials	Depends on State Authority

Applications and enrollment forms, health questionnaires used with application and enrollment forms	Most States collect (Depends on State Authority)
Notices	Depends on State Authority
Self-certification	Depends on State Authority
Data and Supporting Documentation to Ensure Compliance with the Essential Health Benefits (EHB) Package	Depends on State Authority
Data templates such as Plan Benefit template[3]	Depends on State Authority
Issuer response notice	Depends on State Authority
Summary of Benefits and Coverage	Depends on State Authority

Statutory and Regulatory Basis for specific ICRs

The Federal collection of health insurance issuers' form filings of group and individual market products, where states are not enforcing and CMS needs to assume a direct enforcement role in a state, will be used to assess compliance with the following collection requirements under title XXVII of the PHS Act. The regulatory citations reflect provisions covered under the previous PRA. The statutory citations reflect provisions covered under the previous PRA, as well as provisions that were amended by the Affordable Care Act.

(1) Notice to Participants Regarding Special Enrollment Periods

Regulatory basis: 45 CFR 146.117(c) Special Enrollment Periods into Group Health Plans

This section in the HIPAA regulation provides guidance regarding special enrollment rights into group health plans that employees and dependents have under HIPAA. A group health plan is required to provide a description of the special enrollment rights to all employees (those who enroll as well as anyone who declines coverage at the time of enrollment). A model notice with language that explains special enrollment rights is contained at 45 CFR 146.117(c).

(2) Notice of Impaired Financial Capability

Regulatory basis: 45 CFR 146.150 Guaranteed Availability of Coverage for Employers in the Small Group Market and 45 CFR 147.104 Guaranteed Availability of Coverage

[3] The template is approved under OMB Control number 0938-1187 and its collection is approved under OMB Control Number 0938-1086.

Statutory basis: Section 2711(d) of the PHS Act (as numbered prior to the Affordable Care Act) and Section 2702(d) of the PHS Act, as amended by the Affordable Care Act

This section allows a health insurance issuer to deny health insurance coverage in the small group market if the issuer has demonstrated to the applicable state authority (if required by the state authority) or to the Federal government (in cases in which CMS is enforcing this standard in the absence of state authority) that it does not have the financial reserves necessary to underwrite additional coverage. The issuer must also demonstrate that it is applying this denial uniformly to all employers in the small group market in the state consistent with applicable state law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents. Thus, issuers are required to report to the applicable state authority if they are denying coverage in the small group market.

Since 2014, section 2702 of the PHS Act, as amended by the Affordable Care Act, applies to both the individual and group markets.

(3) Federal Review of Policy Forms to Ensure Guaranteed Availability

Regulatory basis: 45 CFR 146.150 Guaranteed Availability of Coverage for Employers in the Small Group Market; 148.120 Guaranteed Availability of Individual Health Insurance Coverage to Certain Individuals with Prior Group Coverage; and 148.126 Determination of an Eligible Individual

Statutory basis: Section 2711(a) and (b) of the PHS Act (as numbered prior to the Affordable Care Act); Section 2702(a) and (b) of the PHS Act, as amended by the Affordable Care Act; Section 2741 of the PHS Act; and Section 2744 of the PHS Act

Under HIPAA, states must ensure guaranteed availability of all products to all small group market employers. Since 2014, section 2702 of the PHS Act, as amended by the Affordable Care Act, applies to both the individual and group markets.

In order to ensure compliance with these provisions, states review policy and application forms, risk rating factors, pooling practices, and agent commission structures during their oversight process to make sure that all individuals and employers have guaranteed availability of coverage.

In states in which CMS is enforcing the individual and group market guaranteed availability requirement, CMS will collect this information to assess compliance with this requirement.

As mentioned previously, since 2014, section 2702 of the PHS Act, as amended by the Affordable Care Act, extends guarantee issue to the individual market. Therefore, the provisions regarding HIPAA guaranteed issue in the individual market to certain HIPAA eligible individuals only remain relevant for issuers in the U.S. territories.

(4) Notice of Intent to Discontinue a Product or Abandon the Market

Regulatory basis: 45 CFR 146.152 (c) and (d) Guaranteed Renewability of Coverage for Employers in the Group Market; 45 CFR 147.106(c) and (d) Guaranteed Renewability of Coverage; and 45 CFR 148.122(d) and (e) Guaranteed Renewability of Individual Health Insurance Coverage

Statutory basis: Section 2712 (c) and (d) of the PHS Act (as numbered prior to the Affordable Care Act); Section 2703(c) and (d) of the PHS Act, as amended by the Affordable Care Act; and Section 2742 of the PHS Act

Issuers are required to report to plan sponsors or individuals if the issuer is discontinuing a particular type of group or individual health insurance coverage.

In addition, issuers are required to report to the state or Federal government, as appropriate, and to plan sponsors or individuals if they are discontinuing all health insurance coverage in the individual or group market, or all markets, in a state.

(5) Federal Review of Policy Forms to Ensure Guaranteed Renewability

Regulatory basis: 45 CFR 146.152 Guaranteed Renewability of Coverage for Employers in the Group Market; 45 CFR 147.106 Guaranteed Renewability of Coverage; and 45 CFR 148.122 Guaranteed Renewability of Individual Health Insurance Coverage

Statutory basis: Section 2712(a) of the PHS Act (as numbered prior to the Affordable Care Act); Section 2703(a) of the PHS Act, as amended by the Affordable Care Act; and Section 2742 of the PHS Act

Under HIPAA, states or the Federal government, as appropriate, will review policies during their oversight process to make sure there is a guaranteed renewability clause in each policy. HIPAA provisions require each issuer in the group or individual market to renew or continue in force coverage at the option of the plan sponsor or individual. Most, if not all, states review policies during their oversight process to make sure there is a guaranteed renewability clause in each policy. Currently, all states require guaranteed renewability as a normal business practice.

Since 2014, section 2703 of the PHS Act, as amended by the Affordable Care Act, applies to both the individual and group markets.

(6) Full Disclosure by Issuers to All Small Employers of Materials on All Products and other Information

Regulatory basis: 45 CFR 146.160 Disclosure of Information by Issuers to Employers

Seeking Coverage in the Small Group Market in the PHS Act Provisions

Statutory basis: Section 2709 of the PHS Act, as amended by the Affordable Care Act

This section is aimed at informing small employers of their right to buy coverage and requires issuers to disclose certain information to employers seeking coverage in the small group market. Information to be provided upon request by a health insurance issuer offering any health insurance coverage to a small employer includes the issuer's right to change premium rates and the factors that may affect changes in premium rates, renewability of coverage, any preexisting condition exclusion, any affiliation periods applied by Health Maintenance Organizations (HMOs), and the geographic areas served by HMOs. The issuer is exempted from disclosing information that is proprietary or trade secret information under applicable law. The information described in this section must be written in language that is understandable by the average small employer and sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage.

(7) Federal Review of Policy Forms to Ensure Coverage for the Essential Health Benefits Package

Regulatory basis: 45 CFR 147.150 Coverage of Essential Health Benefits

Statutory Basis: Section 2707 of the PHS Act, as amended by the Affordable Care Act

This section requires health insurance issuers that offer coverage in the individual or small group market to include the essential health benefits (EHB) package required under section 1302(a) of the Affordable Care Act, which includes coverage of EHB, actuarial value standards, and cost-sharing limits. In order to ensure compliance with these provisions, states may review policy and application forms, benefit structures and quantitative limits, cost-sharing information, and plan data. CMS may collect this same information to assess compliance if it is enforcing this requirement in a state.

B. ICRs relating to Self-funded Non-Federal Governmental Plans Opt-Out Provisions

Under section 2722(a)(2)(E) of the PHS Act, self-funded state and local governmental plans can opt out of some HIPAA requirements with respect to their employees.

(1) Notice to Federal Government of Self-Funded Non-Federal Governmental Plan Opt-Out

Regulatory basis: 45 CFR 146.180 Treatment of Non-Federal Governmental Plans

Statutory basis: Section 2722(a)(2)(E) of the PHS Act

This section of the regulation includes rules pertaining to self-funded non-Federal governmental plans, which are permitted under HIPAA to elect to be exempted on an

annual basis from certain HIPAA requirements in the PHS Act. The regulation establishes the form and manner of the election. A September 21, 2010 memorandum issued by the Office of Consumer Information and Insurance Oversight (OCIIO)[4] discusses the changes the Affordable Care Act made to these opt-out provisions.[5] On May 27, 2014, CMS published the final regulation addressing the HIPAA opt-out election process (79 FR 30240). The final regulation indicated that hard copy election documents via U.S. mail or facsimile will only be accepted through December 31, 2014. The regulation was updated and bulletin issued on July 21, 2014[6] that provides details of the procedures for the opt-out elections by electronic means only.

(2) Notice to Self-Funded Non-Federal Governmental Plan Enrollees of Opt-Out

Regulatory basis: 45 CFR 146.180 Treatment of Non-Federal Governmental Plans

Statutory basis: Section 2722(a)(2)(E) of the PHS Act

A self-funded non-Federal governmental plan making an opt-out election is required to notify plan enrollees, at the time of enrollment and on an annual basis, of the fact and consequences of the election. (See Attachment)

2. Information Users

Individuals and their dependents need this information to take advantage of the rights they have under title XXVII of the PHS Act. States and the Federal government need the information supplied by plans and issuers to properly perform their statutory and regulatory functions under title XXVII of the PHS Act. In a state in which CMS must enforce a provision (or provisions) of title XXVII of the PHS Act, CMS may collect and review health insurance issuers' form filings of group and individual market products for compliance with such provision (or provisions).

CMS processes and records opt-outs submitted by self-funded non-Federal governmental plans. CMS uses this information to verify the validity and timing of submitted opt-outs as well as to determine whether a plan under investigation for potentially violating any provision for which it may opt out is exempt from any of those requirements.

State research and data collection, such as traditional plan information, is used to understand the effect of the Federal government's policy decisions and rules on the health insurance market and assist to inform possible future Federal rule making. In addition, the information is used by the Federal government to provide technical assistance to states for state

[4] Currently CMS' Center for Consumer Information and Insurance Oversight (CCIIO).
[5] Available at http://cciio.cms.gov/resources/files/opt_out_memo.pdf.
[6] Available at http://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/hipaa-exemption-guidance-7212014.pdf .

enforcement purposes.

3. Use of Information Technology

All information collected from form filings must be submitted electronically. CMS or its contractor will analyze the data electronically and communicate with health insurance issuers using an on-line system, email and/or telephone. Health insurance issuers in a state in which CMS must enforce may be expected to submit form filings to CMS. Issuers will only be required to submit in this circumstance if a state is not performing form filing functions to assess compliance with title XXVII of the PHS Act. Issuers are expected to use their data processing systems to generate the certificates and other notices. Opt-out elections must be submitted electronically as well. Information requested from states by the SEC Team may also be submitted electronically.

4. Duplication of Efforts

The ICRs in this supporting statement are the least burdensome way of monitoring market activity and ensuring compliance with these Federal statutory and regulatory requirements. The form filing information collection is similar to the collection that most states use to assess compliance with state law requirements. Forms are readily available and furnished by health insurance issuers as part of their current operations under state law. There is no duplication of efforts for the other ICRs.

5. Small Businesses

Small businesses are not significantly affected by this collection.

6. Less Frequent Collection

This collection is required to fulfill the statutory and regulatory requirements under sections 2723 and 2761 of the PHS Act. This collection ensures compliance with provisions under title XXVII of the PHS Act. In addition, this collection will help to ensure that consumers shopping for, or enrolled in, private, individually purchased or employer-sponsored coverage or in non-Federal governmental plans receive the consumer protections of the market reforms under title XXVII of the PHS Act. If this collection is not conducted in a state that CMS determines lacks authority to enforce or is not substantially enforcing the market reforms and the state does not collect these form filings, consumers in such state may not receive the protections to which they are entitled under these Federal laws.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A Federal Register notice was published on January 31, 2019 (84 FR 733), providing the public with a 60-day period to submit written comments on the ICRs. No comments were received.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these ICRs.

10. Confidentiality

These ICRs do not pose any confidentiality or privacy concerns. The form filing data will not include protected health information as defined under the HIPAA privacy rules. Any request for data that may include protected health information under the HIPAA privacy rules would be required to be de-identified or limited with certain identifiers removed. CMS will work with the health insurance issuers to minimize the burden of de-identifying data. The de-identification of data is standard practice for health insurance issuers when working with other regulatory entities. CMS believes this collection does not require the disclosure of trade secrets or other confidential information.

The Department may receive a Freedom of Information Act (FOIA) request for records submitted to CMS under these ICRs. The Department shall respond to FOIA requests in accordance with the FOIA law, including 45 CFR 5.1 et seq. Information sought in a FOIA request may be exempt from disclosure under an enumerated FOIA exemption. In the event of a FOIA request, the Department will review all requested records to determine if a FOIA exemption applies, regardless of whether the records are marked as confidential. Consistent with the Attorney General's March 9, 2009 Memorandum on FOIA, information will be withheld if CMS reasonably foresees that disclosure would harm an interest protected by one of the FOIA exemptions, or the disclosure is prohibited by law.

Information considered a trade secret or confidential commercial or financial information may be subject to FOIA Exemption Four. If the Department determines that it might have to disclose such information, CMS shall provide the submitter with a predisclosure notification required by 45 CFR 5.65(d), which affords the submitter an opportunity to object to the disclosure. If the Department decides to disclose the records anyway, CMS will provide the submitter with advance notice of the disclosure as further required by 45 CFR 5.65(d).

11. Sensitive Questions

These ICRs involve no sensitive questions.

12. Burden Estimates (Hours & Wages)

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to

derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[7] Table 2 below presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage. As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent.

TABLE 2: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hour)	Fringe Benefits and Overhead ($/hour)	Adjusted Hourly Wage ($/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43-6014	$17.75	$17.75	$35.50
Business Operations Specialists	13-1199	$36.42	$36.42	$72.84
General and Operations Managers	11-1021	$59.35	$59.35	$118.70
Compensation and Benefits Manager	11-3111	$62.50	$62.50	$125.00

A. ICRs relating to Group and Individual Market Reforms

Federal Review of Information to Ensure Compliance with requirements under title XXVII of the PHS Act

Federal Review of Form Filings

The Federal collection of health insurance issuers' form filings of group and individual market products will be used to assess compliance with title XXVII of the PHS Act (including ICRs in B1.a. through B1.j. in this supporting statement). As mentioned previously, this collection will only be required if CMS makes a determination that a state lacks authority to enforce or is not substantially enforcing any requirement under title XXVII of the PHS Act. As part of enforcement, CMS may require health insurance issuers in a state to submit form filings to CMS. In most states, this collection is similar to requirements under state law. Most states require issuers to submit form filings and as such, form filings are readily available and furnished by issuers as part of their current operations under state law. In states where this collection is already required, this ICR is exempt

[7] See May 2017 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at https://www.bls.gov/oes/current/oes_nat.htm.

because it does not meet the definition of a collection of information, as outlined in 5 CFR 1320.3(c). Currently there are four states in which CMS directly enforces one or more provisions.

Issuer burden - Federal Compliance Review

For purposes of determining a burden estimate for enforcing these requirements, we reviewed the number of issuers that submitted forms during 2018 and the total number of forms submitted during 2018 in the existing four direct enforcement states. CMS estimates that 52 issuers in these four states will each submit, on average, 50 forms to CMS. Since issuers already prepare these forms, issuers will only incur the burden to submit the forms. It is estimated that on average for each issuer, an administrative assistant will need 3 hours (at $35.50 per hour) and a business operations specialist will need 1 hour (at $72.84 per hour) to submit the forms to CMS. The total annual burden for each issuer will be 4 hours, with an equivalent cost of approximately $179 per issuer. Therefore, the total annual burden for 52 issuers will be 208 hours with an equivalent cost of approximately $9,326.

Issuers/respondents will need to update or create new forms and respond to notices with issues found during the form filing review after the initial form filing has been submitted to CMS. If an issuer/respondent wants to create new offerings in the market, a more complete submission, similar to the initial submission, is required. We anticipate that for each issuer, a business operations specialist (at $72.84 per hour) will need 2 hours and a manager will need 1 hour (at $118.70 per hour) for this activity annually, with an equivalent cost of approximately $264. The total annual burden for all 52 issuers will be 156 hours, with an equivalent cost of approximately $13,748.

Generally, form filings are readily available and disclosed by health insurance issuers as part of their current operations under state law. Most states already require health insurance issuers to submit form filings (for insurance products marketed and sold in the state) to the state for review for compliance with state laws, in the absence of any Federal requirement. Regardless of whether the state requires form filings to be submitted for review or use, all states require the issuer to develop forms for issuance to plan participants. Therefore, in states where this collection is already required, this ICR is exempt because it does not meet the definition of a collection of information, as outlined in 5 CFR 1320.3(b)(3).

Federal Review of State Information Related to State Compliance and Enforcement of Provisions relating to Title XXVII of the PHS Act

State Burden - Reporting

The burden associated with this ICR is the time involved for states to provide to CMS state information relating to state compliance and enforcement of provisions relating to title XXVII of the PHS Act. CMS may need this information in order to determine whether a state has the authority and is substantially enforcing the new requirements under title XXVII

of the PHS Act. We estimate that most, if not all, state insurance departments will have this information readily available as a normal business practice. Therefore, the burden associated with this ICR is exempt from the PRA under 5 CFR 1320.3(b)(2).

Total burden hours are identified below for each of the specific ICRs covered by the group and individual market regulations.

(1) Notice to Participants Regarding Special Enrollment Periods

Issuer Burden--Notice Issuance

Under the HIPAA group market regulations, a plan must provide all employees with a notice describing special enrollment rights at or before the time the employee is initially offered the opportunity to enroll in the plan. The HIPAA final regulations provide model language that can be used to satisfy the special enrollment notice requirements.

We believe that plans have already incorporated special enrollment language into their plan enrollment materials. Thus, the cost of the special enrollment notice is assumed to be negligible compared to the overall cost of providing plan enrollment materials and is therefore not estimated.

Issuer Burden - Federal Compliance Review

Federal enforcement of this notification requirement will be done through review of policy forms and supporting materials (burden described above) or on a complaint basis or through a focused audit/investigation process, which is exempt from the PRA as described above. (See background discussion of varying Federal enforcement situations.)

(2) Notice of Impaired Financial Capability

Issuer Burden - Federal Compliance Review

If CMS is enforcing this requirement in a state in the absence of state authority, issuers will report impaired financial capacity directly to CMS. We therefore estimate that issuers in one state will be required to report directly to CMS if they encounter financial difficulties and since states closely monitor the financial health of companies operating in the state, we estimate that fewer than 10 issuers will need to submit notice of impaired financial capacity directly to CMS on an annual basis.

Our estimate is based on the following analysis. The National Association of Insurance Commissioners (NAIC) maintains a database of solvency reports for use by its members. Historically, such issuer reports have been under the threshold of 10 companies annually.

Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

(3) Federal Review of Policy Forms to Ensure Guaranteed Availability

Under HIPAA, states must ensure guaranteed availability of all products to all small group market employers. Since 2014, section 2702 of the PHS Act, as amended by the Affordable Care Act, applies to both the individual and group markets.

In order to ensure compliance with these provisions, states review policy and application forms, risk rating factors, pooling practices, and agent commission structures during their oversight process to make sure that all individuals and employers have guaranteed availability of coverage. In states in which CMS is enforcing the individual and group market guaranteed availability requirement, CMS will collect this information to assess compliance with this requirement.

Issuer Burden - Federal Compliance Review

The burden to issuers for providing the information to CMS for this review is included in the burden for Federal review of form filings above.

Enforcement of this requirement will be done through review of policy forms and supporting materials (burden described above) or on a complaint basis or through a focused audit/investigation process, which is exempt from the PRA as described above. (See background discussion of varying Federal enforcement situations.)

(4) Notice of Intent to Discontinue a Product or Abandon the Market

Issuer Burden - Notice Issuance

Under the HIPAA final regulations, issuers are required to provide notice to plan sponsors or individuals if the issuer is discontinuing a particular type of individual or group health insurance coverage or all health insurance coverage in the individual or group market, or all markets, in a state.

Issuer Burden - Federal Compliance Review

If CMS is enforcing this requirement in a state in the absence of state authority, issuers will report market abandonment directly to CMS. We estimate that no issuers in any state will be required to report directly to CMS if they choose to withdraw entirely from the market place. Therefore, we estimate that fewer than 10 issuers will need to submit notice of

market abandonment directly to CMS on an annual basis. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

(5) Federal Review of Policy Forms to Ensure Guaranteed Renewability

Issuer Burden- Federal Compliance Review

If CMS is enforcing the guaranteed renewability requirements in a state, we will enforce compliance through policy review under Federal enforcement. The burden estimate associated with the policy review is described above.

(6) Full Disclosure by Issuers to All Small Employers of Materials on All Products and Other Information

Issuer Burden - Full Disclosure to Small Employers

We anticipate that approximately 387 issuers in the small group market will be required to provide disclosure to small employers on an annual basis. Based on experience to date, we estimate that for each issuer a business operations specialist will need approximately 1.5 hours (at $72.84 per hour) and a manager will need 0.5 hours (at $118.70 per hour) to develop and update the standard information related to the general description of benefits and premiums on an annual basis and include this information in their marketing materials and related policy information. The total annual burden for each issuer will be 2 hours, with an equivalent annual cost of approximately $169. The total annual burden for all issuers will be 774 hours, with an equivalent cost of approximately $65,252. This estimate is based on the belief that, beyond the initial modification to the marketing materials, the burden associated with this ICR will be low in subsequent years.

Issuer Burden - Federal Compliance Review

If CMS is enforcing this disclosure requirement in a state, we will enforce compliance through policy review under Federal enforcement. The burden estimate associated with the policy review function is described above.

(7) Federal Review of Policy Forms to Ensure Coverage for the Essential Health Benefits Package

Issuer Burden - Federal Compliance Review

If CMS is enforcing this coverage requirement in a state, we will enforce compliance through policy review, including review of policy and application forms, benefits structures and quantitative limits, cost-sharing information, and plan data, under Federal enforcement. The burden estimate associated with the policy review function is described above.

B. ICRs relating to Self-Funded Non-Federal Governmental Plans Opt-Out Provisions

(1) Notice to Federal Government of Self-Funded Non-Federal Governmental Plan Opt-Out
Plan Burden - Preparation of Opt-Out Election Notice to CMS

The burden associated with this ICR is the time involved for a plan electing to opt out of certain requirements to complete the model notification in the attachment and forward it to CMS through CMS' Health Insurance Oversight System (HIOS). Based on recent experience, we anticipate that approximately 290 plans will actively opt out at any given time. We estimate that for each plan, a compensation and benefits manager will need 15 minutes (at a cost of $125 per hour) annually to fill out and electronically submit the form with an equivalent cost of approximately $31. The total annual burden for all 290 plans will be approximately 73 hours, with an equivalent annual cost of approximately $9,063. This includes the time required by the individual signing the certification to conduct a thorough review of the election contents.

Plan Burden - Federal Compliance Review

CMS will enforce compliance with the notice to CMS requirement relating to the opt-out election on a complaint basis or through a focused audit/investigation process, which is exempt from the PRA as described above.

(2) Notice to Self-Funded Non-Federal Governmental Plan Enrollees of Opt-Out
Plan Burden - Preparation and Dissemination of Opt-Out Notice to Plan Enrollees

(a) The approximately 290 self-funded non-Federal governmental plans that have made this election are required to provide notifications to their enrollees on an annual basis. CMS developed a model with standard language that may be incorporated into a plan's existing policy documents. Therefore, we estimate for each plan, an administrative assistant will need 15 minutes (at a cost of $35.50 per hour) to develop and update the CMS standardized disclosure statement annually, with an equivalent cost of approximately $9. The total annual burden for all plans will be approximately 73 hours, with an equivalent cost of approximately $2,574.

(b) For 290 self-funded non-Federal governmental plans, an estimated 41,760 notices need to be produced annually. The notice will be provided with other plan documents at no additional cost. The notice will be 1 page long, and the cost of materials and printing is estimated to be $0.05 per page. Therefore, the total annual cost of printing all notices is estimated to be approximately $2,088.

Plan Burden - Federal Compliance Review

CMS will enforce compliance with the opt-out notification to enrollees' requirement on a complaint basis or through a focused audit/investigation process, which is exempt from the

PRA as described above.

C. ICRs relating to State Engagement Coordination and Compliance Monitoring

CMS anticipates requesting information from states and the District of Columbia approximately 6 times annually, with some requests going to a subset of states and receiving 175 responses annually. We anticipate that for each request, a business operations specialist will need 2 hours (at $72.85 per hour) and a manager will need 0.5 hours (at $118.70 per hour) to conduct any research and prepare a response, with a total burden of 2.5 hours and an equivalent cost of approximately $205. The total annual burden for all 175 responses will be approximately 438 hours with an equivalent annual cost of approximately $35,880.

Table 3: Estimated Annual Average Burden

Forms (If necessary)	Type of Respondent	Number of Respondents	Number of Responses	Average Burden hours per Response	Total Burden Hours	Total Labor Cost
Form Filing Submission	Issuers	52	52	4	208	$9,326
Form Filing - New Submission	Issuers		52	3	156	$13,748
Small Employers - Guaranteed Availability	Issuers	387	387	2	774	$65,252
Opt-Out Election Notice to CMS	Non-Federal Governmental plans	290	290	0.25	72.5	$9,063
Opt-Out Notice to Members			41,760	0.25	72.5	$2,574
State Engagement Coordination	States and the District of Columbia	51	175	2.5	437.5	$35,880
Total		780			1,720.5	$135,842

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

These ICRs involve notification requirements and other information exchanges: i) between plans/issuers and individuals covered under the plan/issuers' policies; ii) between issuers and states or the Federal government enforcing standards under title XXVII of the PHS Act and other Federal laws and regulations; and iii) between states and the Federal government. Generally, the Federal government becomes involved only if a state notifies CMS that it lacks authority or is otherwise not enforcing one or more of these provisions, or if CMS has determined that a state is not substantially enforcing issuer compliance with these requirements. The collection and review of state information to assess state compliance and enforcement relating to title XXVII of the PHS Act, where necessary, will be conducted in-house and will be at no additional cost to the Federal government.

The costs associated with this collection are dependent on whether and how CMS becomes involved in enforcement in a state, under the following circumstances: (a) a state notifies CMS that the state is not enforcing the group and individual market reforms or invites CMS to enforce these provisions within its borders; or (2) CMS' determination that a state lacks authority to enforce or is not substantially enforcing one or more provisions of the group or individual market reforms.

In the event that a state notifies CMS that it lacks authority to enforce or is not enforcing (or invites CMS to enforce) the group and individual market reforms, CMS may enforce those requirements in collaboration with the state. Likewise, in the event that the state does not collaborate with CMS in the enforcement of these requirements, there may additional cost to CMS.

In either situation, where necessary, CMS will use an external contractor to review form filings to assess compliance with provisions under title XXVII of the PHS Act. We estimate that the cost to review approximately 2,600 form filings (52 respondents with an average of 50 forms per response) is not anticipated to exceed $1.9 million per year. The contract will be managed by staff at the GS-14 level (with an annual salary of $114,590 at the Washington D.C. area). We estimate that managing this contract is not anticipated to exceed 500 hours per year. The total cost for form filing reviews is estimated to be $1,927,455.

The information collected by the SEC Team will be reviewed by CMS staff, with an average time of 1 hour per review. Therefore, the total estimated time needed for all reviews will be 175 hours annually, with 125 hours done by staff at GS-13 level (with an annual salary of $96,970 at the Washington D.C. area) and 50 hours by staff at and GS-14 level (with an annual salary of $114,590 at the Washington D.C. area). The total annual cost for all reviews will be approximately $8,553.

The total annual cost to the federal government for form filing reviews and review of information received by SEC Team will be approximately $1,936,008.

15. Changes to Burden

There are program changes in this collection as a result of implementing new requirements associated with the state engagement coordination. These new requirements increased the burden by 438 hours.

The estimated burden related to form filing submissions has decreased by 399 hours (from 763 to 364) due to the reduction in the estimated number of issuers that submit forms for CMS' review. The estimated burden related to full disclosure by issuers to all small employers of materials on all products and other information has decreased by 74 hours (from 848 to due to a reduction in the estimated number of issuers affected by this requirement. The estimated burden related to opt-out notices has decreased by 798.5 hours (from 943.5 hours to 145 hours) due to a reduction in the estimated number of plans opting out.

Although new requirements increased the burden hours by 438 hours, the overall burden hour total has been reduced by hours (from 2,555 to 1,720) due to the decrease in the number of respondents (from 983 issuers to 780 issuers).

16. Publication/Tabulation Dates
CMS periodically publishes lists of valid opt-outs for public review.

17. Expiration Date

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

ATTACHMENT: MODEL NOTICE TO ENROLLEES IN A SELF-FUNDED NON-FEDERAL GOVERNMENTAL GROUP HEALTH PLAN