Supporting Statement for Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act

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 with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions.

This Information Collection Requirement (ICR) is a reinstatement of a collection which expired on September 30, 2012 (OMB#: 0938-0702 and OMB#: 0938-0703) with minimal changes but for the additions to reflect laws passed since the previous collection document was approved. This reinstatement with changes combines the two expired collections into one package.

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

Title XXVII of the PHS Act includes provisions regarding the individual and group markets. 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 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 offer maternity coverage to pay for 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 addressed 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 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 prohibits certain large group health plans and health insurance issuers from imposing requirements and limitations on mental health or substance use disorder benefits that are more restrictive than the predominant requirements applied to substantially all medical/surgical benefits.

- 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, Pub. L. 111-148, was enacted on March 23, 2010; and the Health Care and Education Reconciliation Act of 2010, Pub. L. 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 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 who 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.[1]

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

1 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.

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 at 45 CFR 150.203. These regulations provide for two possibilities for direct enforcement by CMS. The first is a situation in which the 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 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.

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, we are submitting this PRA to cover ICRs that may fall outside of the narrow exemptions, as well as for transparency.

4. Self-funded Non-Federal Governmental Plans

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 opt-out.

B. Justification

Need and Legal Basis

1. ICR relating to Group and Individual Market Reforms

Sections 2723 and 2761 of the PHS Act directs 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 with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions.

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 cooperative 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 may 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.

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 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

The previous PRA submission for this collection included two ICRs in the HIPAA group market regulations that are regulatory requirements. The first is Notice of Preexisting Condition Exclusion (see B1.b). This ICR is not specifically required by the statute, but carries out the intent of the statute that individuals should know when they are being affected by the policy. The second is Notice to Participants Regarding Special Enrollment Periods (see B1.c). This ICR advises the individual of important rights they may be able to exercise in the future. This ICR is not specifically required by the statute, but carries out the intent of the statute that individuals should know of their special enrollment rights.

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 is needed 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.

a. Certificates and Disclosure of Prior Coverage

Regulatory basis: 45 CFR 146.115 Certification and Disclosure of Previous Coverage; and 148.124 Certification and disclosure of coverage
Statutory basis: Section 2701(e) of the PHS Act (as numbered prior to the Affordable Care Act); Section 2704(e) of the PHS Act, as amended by the Affordable Care Act; and Section 2743 of the PHS Act

This ICR implements statutorily prescribed requirements necessary for an individual to establish prior creditable coverage so that any allowable preexisting condition exclusion that a plan may wish to apply to the individual may be reduced or totally eliminated. This ICR is based on current statutory and regulatory requirements. This ICR will be revised in the future to reflect changes in the related legal requirements, as appropriate.

This is accomplished primarily through the issuance of certificates of prior coverage by plans or issuers that provide health insurance coverage. This ICR also covers the requests that certain plans will make regarding additional information they require because they are using the Alternative Method of Crediting Coverage. Finally, this ICR includes the occasional circumstances where a participant is unable to secure a certificate and needs to provide some supplemental form of documentation in order to establish prior creditable coverage.

This ICR involves use of data that employers or issuers generally have on hand and submit to states annually. Consistent with the final HIPAA group and individual market portability regulations, published December 30, 2004, the certificate must include an educational Statement regarding HIPAA portability rights.

Model educational language is provided in the model certificate. This eliminates the burden on issuers of developing language to satisfy this requirement. Use of the model certificate has been required as of the first day of all plan years beginning on or after July 1, 2005. It satisfies the requirements of 45 CFR 146.115(a)(3)(ii). A second model certificate has been authorized by the Secretary of Health and Human Services for State Medicaid programs.

In addition to these model certificates, the Departments have a different model certificate for group health plans and health insurance issuers in the preamble to the proposed rules for HIPAA health coverage portability, also issued December 30, 2004. That model certificate and a parallel one for State Medicaid programs include an additional paragraph in their educational Statements regarding coordination with rules under the Family and Medical Leave Act. Issuers and State Medicaid programs may use those model certificates in place of the model certificates in the HIPAA final regulations, in order to satisfy the requirements of 45 CFR 146.115(a)(3)(ii).

Plans and issuers may use the model disclosure form in reporting specific benefits to issuers that use the alternative method of crediting coverage.

b. Notice of Preexisting Condition Exclusion

Regulatory basis: 45 CFR 146.111(c) General Notice of Preexisting Condition Exclusion; and 45 CFR 146.111(e) Individual Notice of Period of Preexisting Condition Exclusion

This regulatory authority is aimed at ensuring that plan participants have notice of the imposition of preexisting condition exclusions on them. This will be revised and potentially eliminated to reflect changes in the related legal requirements, as appropriate. To ensure compliance with this regulatory authority, states require issuers to submit sample notices and/or deal with noncompliance on complaint-based audits.

This ICR concerns the disclosure requirements on those issuers of group health coverage that use preexisting condition exclusion provisions. Model language that issuers may use to notify participants about preexisting condition exclusions was included in the 2004 HIPAA final regulations. This ICR is based on current statutory and regulatory requirements. This ICR will be revised in the future to reflect changes in the related legal requirements, as appropriate.

c. Notice to Participants Regarding Special Enrollment Periods

Regulatory basis: 45 CFR 146.117(c) Special Enrollment Periods

This section in the HIPAA regulation provides guidance regarding special enrollment rights 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 CFR146.117(c).

d. Notice of Impaired Financial Capability

Regulatory basis: 45 CFR 146.150 Guaranteed Availability of Coverage for Employers in the PHS Act Group Market Provisions
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 discontinuing coverage in the small group market.

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

e. Federal Review of Policy Forms to Ensure Guaranteed Availability

Regulatory basis: 45 CFR 146.150 Guaranteed Availability of Coverage for Employers in the PHS Act Group Market Provisions; 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. In 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 small employers have guaranteed availability of coverage in the small group market.

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, in 2014, section 2702 of the PHS Act, as amended by the Affordable Care Act, extends guarantee issue to the individual market. Therefore, the current provisions regarding HIPAA guaranteed issue and the individual market only remain relevant until 2014. Under HIPAA individual market provisions, states are given the flexibility either to enforce the Federal requirements set forth in 148.120 (commonly referred to as the Federal "fallback" rules) or to implement an alternative mechanism, under state law, that achieves the statutory goal of providing individuals who meet certain criteria specified in HIPAA (eligible individuals) with access to a choice of individual health insurance, or comparable coverage, without preexisting condition exclusions. However, a state could choose to do neither, resulting in Federal enforcement of the individual market regulations under HIPAA. Currently, 42 states have implemented an alternative mechanism under 148.128. Eight states and four territories have opted to enforce the Federal fallback requirements under 148.120. CMS, therefore, is currently not enforcing these individual market provisions in any state.

Every three years, the statute requires all states using alternative mechanisms to resubmit their alternative mechanisms. In the absence of an alternative mechanism, issuers may limit the products they make available to eligible individuals to two policies. The two policies must be designed for, made generally available to, actively marketed to, and actually enroll both eligible individuals and others. The two policies may be an issuer's two most popular policies, based on premium volume, or two representative policies. The latter must meet several additional requirements.

Section 148.126 requires issuers to determine whether individuals are eligible individuals. In this section, issuers must maintain records for those individuals whom they determine are not HIPAA eligible individuals. We estimate that records for 50 individuals for each of 1,000 issuers, or 50,000 records will be maintained in 2012 and 2013. At 20 minutes per record, this represents a total annual burden of 16,667 hours for 2012 and 2013. There is no burden for this requirement in 2014.

f. Notice of Intent to Discontinue a Product or Abandon the Market

Regulatory basis: 45 CFR 146.152 Guaranteed Renewability of Coverage for Employers in the PHS Act Group Market Provisions
Statutory basis: Section 2712 (c) and (d) of the PHS Act (as numbered prior to the Affordable Care Act); and Section 2703(c) and (d) of the PHS Act, as amended by the Affordable Care 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.

g. Federal Review of Policy Forms to Ensure Guaranteed Renewability

Regulatory basis: 45 CFR 146.152 Guaranteed Renewability of Coverage for Employers in the PHS Act Group Market Provisions; and 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 individual market provisions require each issuer in the individual market to renew or continue in force, at the option of the individual, all individual health insurance coverage. All states (whether they are enforcing the Federal fallback requirements or implementing an alternative mechanism with respect to guaranteed availability) 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.

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

h. 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 2713 of the PHS Act (as numbered prior to the Affordable Care Act); and 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 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.

i. Federal Review of Policy Forms to Ensure Coverage for the Essential Health Benefits Package

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 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 policy in a state.

2. ICR 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.

a. 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 some or all of HIPAA's requirements in the PHS Act (other than those pertaining to the issuance of certificates of creditable coverage). 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)[2] discusses the changes the Affordable Care Act made to these opt-out provisions.[3]

Practical experience has indicated that self-funded non-Federal governmental plans desiring to opt out of some or all of the HIPAA provisions for which the opt-out applies need further guidance concerning how to implement this election. We are therefore providing an updated model document that plans may use in preparing a submission to CMS. However, entities desiring to opt out may submit the information in any format that meets the minimal data requirements set forth in the regulation. (See Attachment)

2 Currently CMS's Center for Consumer Information and Insurance Oversight (CCIIO).
3 *Available at* http://cciio.cms.gov/resources/files/opt_out_memo.pdf.

b. Notice to 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 the election to opt out of some or all of the HIPAA requirements (other than the requirement to provide certificates of creditable coverage) is required to notify plan enrollees, at the time of enrollment and on an annual basis, of the fact and consequences of the election. We are providing an updated model notice to plan enrollees explaining the election to opt out of HIPAA standards. (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).

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 email and phone. 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. Telephonic interchange of certificate information is permitted, in lieu of a certificate, if all parties agree.

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. This information collection is similar to the collection that most states use to assess compliance with state law requirements. If a state requires form filings, form filings are readily available and disclosed by health insurance issuers as part of their current operations under state law. States use form filings to monitor compliance with state law provisions.

5. Small Businesses

Small businesses are not significantly affected by this collection because CMS (unlike the Department of Labor or the Treasury) only regulates health insurance issuers, and health plans

sponsored by states and local governments, not health plans sponsored by small employers. Generally, form filings are readily available and disclosed by health insurance issuers as part of their current operations under state law. No capital costs are required for this effort. The electronic distribution of information should also ease burden among health insurance issuers.

As discussed in the Web Portal interim final rule (75 FR 24481), the Department of Health and Human Services (HHS) examined the health insurance industry in depth in the Regulatory Impact Analysis prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis, HHS determined that there were few if any insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for ''small'' business established by the Small Business Association (SBA). Currently, the SBA size threshold is $7 million in annual receipts for both health insurers (North American Industry Classification System, or NAICS, Code 524114) and TPAs (NAICS Code 524292). We conclude that the vast majority of health insurance issuers that will be impacted by this collection are not small businesses.

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 will not receive the protections to which they are entitled under these Federal laws.

7. Special Circumstances

N/A. There are no special circumstances.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on November 21, 2012 at 77 FR 69846. The Department received one comment in response to the 60-day notice and supporting statement. The commenter expressed support for the continued application of the PHS Act enforcement framework and recommended that HHS work with states to assure a workable regulatory framework for health plans and collect from issuers only the minimum information necessary to ensure compliance. The commenter also asked for guidance clarifying the privacy and security of information. In response to the comment, CMS has added language clarifying that CMS will only collect the minimum information necessary to ensure compliance with the provision (or provisions) for which CMS must enforce. CMS has also added language clarifying the privacy

and security of information under the HIPAA privacy rules and the Freedom of Information Act (FOIA).

The National Association of Insurance Commissioners (NAIC) conducted a survey of the states' enforcement authority. In addition, CMS has researched states' enforcement authority and states have shared their regulatory experiences with CMS.

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. The Department believes this collection does not require the disclosure of trade secrets or other confidential information. In addition, the data provided for certificates of creditable coverage relates to periods of coverage, not medical conditions that might or might not be paid for by the health coverage.

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 Estimate (Hours & Wages)

1. ICR 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 disclosed by issuers as part of their current operations under state law. 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(c). Because we do not know in which states CMS will enforce one or more provisions, we cannot determine what, if any, collection would fit under this exemption. Therefore, we have drafted this PRA Statement to estimate burden for an average state.

Issuer burden--Federal Compliance Review

For purposes of determining a burden estimate for enforcing these requirements, we reviewed the most recent data from the U.S. Census Bureau and selected a mid-sized state based on population. Since CMS does not know which or how many states, if any, will not enforce the requirements under title XXVII of the PHS Act, we estimate the burden for an average state. Accordingly, direct enforcement by CMS in more than one state would be a multiple of that burden. Based on past experience, we estimate that a mid-sized state has 83 issuers/respondents that would be required to submit form filings to CMS. We estimate that issuers/respondents in that state would file an average of 20 policies, each requiring one-hour's burden to prepare the necessary documentation. The total burden associated with these requirements, 1,660 hours, is based on the assumption that issuers/respondents are required to submit all products being actively marketed in the group and individual market. In addition, issuers/respondents will only need to file any amendments to these form filings 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 issuers/respondents will each require on average three hours for this activity annually. The burden for this activity is 249 hours. 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. 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).

The estimated total hour burden and equivalent cost for the collections of form filings in one state is as follows:

Based on the estimate for one state, CMS estimates 1,909 burden hours and an equivalent cost of about $58,549. This estimate is made assuming health insurance issuers will need to submit form filings, approximately 20 forms per company and one hour to produce each form, and in the event of a material change to a policy form, three hours annually ((83 respondents x 20 responses/respondent x 1 hours per response) + (83 respondents x 3 hours per response) = 1,909 in 2012, 2013, and 2014.

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.

a. Certificates and Disclosure of Prior Coverage

Issuer Burden--Certificate Issuance

We anticipate that approximately 1,400 issuers will be required to produce 34,900,000 certifications of creditable coverage per year based on the model certificate, and that this will require, on average, 5 minutes per certificate for a total burden of 2,908,333 hours. Our estimate of 1,400 issuers includes commercial insurers, Health Maintenance Organizations and Preferred Provider Organizations. Total cost is estimated to be $89,198,573. The amount of burden hours per respondent has not changed. For the individual market, the anticipated maximum annual burden hours for 2012, 2013 and 2014[4] is 835,517, and an anticipated cost of $25,625,306.

4 These burden estimates are based on current statutory and regulatory requirements. These estimates may be

The HIPAA final regulations include numerous provisions that reduce plans' and issuers' costs of providing certificates. For example, the Departments have provided a suitable educational Statement for use by plans and issuers, thereby eliminating any need to develop their own. Other instances in which the Departments attempted in the HIPAA final regulations to minimize costs include: not imposing the obligation to issue certificates on an intermediate issuer when an individual changes options under the same group health plan; allowing telephonic certification when issuers and the individual agree; holding the plan blameless if an issuer fails to send certificates that were required by contract between plan and issuer; requiring only the last continuous period of coverage be listed on automatic certificates; allowing the period of coverage contained in on-request certification to be limited to all periods ending within 24 months before the date of the request; permitting a combined certificate for families under certain circumstances and delaying an automatic certificate for a dependent until they know or should know of the dependent's ending of coverage under the plan.

The time estimate for providing certificates includes the time required to gather the pertinent information, create a certificate, and mail the certificate to the plan participant. We believe that, as a routine business practice, the plans and issuers' administrative staff has the necessary information readily available to generate the required certificates. In addition, we have determined that the majority of plans and issuers have or will have the capability to automatically computer generate and disseminate the necessary certification when appropriate. In addition to the certificates of creditable coverage that self-funded non-Federal governmental plans provide either by themselves or by their third party administrators, these estimates also include the certificates issuers must provide on behalf of fully insured state and local governmental health plans, since we anticipate that most, if not all fully insured state and local governmental health plans will contract with an issuer to produce the certificate.

Issuer Burden--Federal Compliance Review

If CMS is enforcing the certificate of creditable coverage requirements in a state, we will enforce compliance through collections of policy forms (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.)

b. Notice of Preexisting Condition Exclusion

Issuer Burden--Notice Issuance

This ICR has two components: (1) a general notice to all participants at the time of

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revised in the future to reflect changes in the related legal requirements, as appropriate.

enrollment stating the terms of the plan's preexisting condition provisions, the participant's right to demonstrate creditable coverage, and that the plan or issuer will assist in securing a certificate if necessary; and (2) notice (to the individual) by the issuer of its determination that an exclusion period applies to an individual, and the length of that period. Note that this ICR will be eventually eliminated to reflect changes in the related legal requirements, as appropriate.

(1) The estimates assume that the general notice is a component of standard plan materials and requires one-third of a sheet of paper. Using a printing/copying cost of $0.05 per page, the cost per notice is $0.0167. An example in the HIPAA final regulations provides sample language that issuers may use. The notice outlines the existence and terms of any preexisting condition exclusion under the plan and the rights of individuals to demonstrate creditable coverage, and a person to contact for additional information. We anticipate that 700 issuers will be required to include within plan materials approximately 400,000 notices in 2012 and 400,000 notices in 2013[5]. These estimates include the notices required by self-funded non-Federal governmental plans either by themselves or by their third party administrators or by issuers on behalf of fully insured state and local government health plans, since we anticipate that most, if not all fully insured state and local governmental health plans will contract with an issuer to develop the notice.

(2) With respect to the second notice to the individual of a period of preexisting condition exclusion after the application of any prior creditable coverage, we view these 7,080 notices as a subset of the 400,000 general notices included yearly in plan materials. We estimate 2 minutes of clerical time plus $0.47 for printing, envelopes and postage for a total cost of $1.05 per notice. The total hour burden was calculated at 236 hours per year for 2012 and 2013, or $7,238 for both general and individual notices. These estimates include the notices by self-funded non-Federal governmental plans either by themselves or by their third party administrators or by issuers on behalf of fully insured state and local government health plans, since we anticipate that most, if not all such plans will contract with an issuer to develop the notice.

Issuer Burden--Federal Compliance Review

If CMS is enforcing these notification requirements as part of Federal enforcement in a state, we will enforce compliance 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.)

5 These burden estimates are based on current statutory and regulatory requirements. These estimates may be revised in the future to reflect changes in the related legal requirements, as appropriate.

c. 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 the vast majority of plans have incorporated special enrollment language into their plan enrollment materials. Thus, the cost of the special enrollment notice is assumed to be a minor component of the overall cost of providing plan enrollment materials. We estimate that the special enrollment notice itself requires one-third of a sheet of paper. Using a printing/copying cost of $0.05 per page, the cost per notice is $0.0167.

The annual cost for 1,400 non-Federal governmental plans to provide 1,600,000 notices is $26,667. These estimates include the notices required by self-funded plans or their third party administrators or by issuers on behalf of fully insured state and local governmental health plans.

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.)

d. 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 NAIC maintains a database of solvency reports for use by its members. Historically, such issuer reports have been under the threshold of 10 companies. Therefore, this ICR is exempt because it does not meet the definition of a collection of information, as outlined in 5 CFR 1320.3(c).

e. 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. In 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 small employers have guaranteed availability of coverage in the small group market. 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—Records

Section 148.126 requires issuers to determine whether individuals are HIPAA eligible individuals. Issuers are required to maintain records for those individuals whom they determine are not HIPAA eligible individuals. For the individual market, maintaining records for those individuals that issuers determine are not HIPAA eligible, the estimated burden is 1,000 issuers x 50 individuals on average x 20 minutes=16,667 hours for 2012 and 2013. There is no burden for this requirement in 2014.

Issuer Burden--Federal Compliance Review

In an average state, we estimate that 83 issuers would need to file an average of 20 policies, each requiring one-hour's burden. The total burden associated with these requirements is 1,660 hours.

After the comprehensive submission has been made, issuers will only need to file changes to these policy forms as they plan to make them. If an issuer wants to create new offerings in the market, a more complete submission, similar to the initial submission, will be required. We anticipate that the 83 issuers will each require on average three hours for this activity annually. The total burden is 249 hours.

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.) The burden associated with state enforcement of an alternative mechanism under state laws and regulations is exempt from the PRA, as stated above.

f. Notice of Intent to Discontinue a Product or Abandon the Market

Issuer Burden--Notice Issuance

Under the HIPAA final regulations, issuers are required to report 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 product discontinuance or market abandonment directly to CMS. We estimate that issuers in one state will be required to report directly to CMS if they choose to reduce their offerings or withdraw entirely from the market place. Based on our contacts with individual states and the NAIC, we believe that the one state currently under Federal enforcement closely monitors product offerings by its issuers operating in their state. Therefore, we estimate that fewer than 10 issuers will need to submit notice of product discontinuance or market abandonment directly to CMS on an annual basis. Therefore, this ICR is exempt because it does not meet the definition of a collection of information, as outlined in 5 CFR 1320.3(c).

g. 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.

h. 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 1,200 issuers will be required to provide disclosure to small employers on an annual basis. Based on experience to date, we estimate this time to be approximately 2 hours for each issuer 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. We have estimated the total burden associated with this activity to be 2,400 hours. This estimate is based on the belief that, beyond the initial modification to the marketing materials, the burden associated with this ICR will be negligible 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.

i. 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.

2. ICR relating to Self-funded Non-Federal Governmental Plans Opt Out Provisions

a. 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 HIPAA and other related requirements to complete the model notification in the attachment and forward it to CMS. The estimated 650 plans have actively opted out at any given time. Therefore, we estimate an annual burden of 15 minutes x 650 plans to fill out the form for a total burden of 163 hours. We have over 1,000 plans in our database for the opt-out provision, including both active and inactive electors.

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.

b. Notice to Non-Federal Governmental Plan Enrollees of Opt-Out

Plan Burden--Preparation and Dissemination of Opt-Out Notice to Plan Enrollees

(1) The up to 650 self-funded non-Federal governmental plans that have made this election are required to provide notifications to their enrollees on an annual basis. Since CMS developed a model with standard language that may be incorporated into plans' existing policy documents, we estimate no burden to the public to develop and update the CMS standardized disclosure statement annually.

(2) For 650 non-Federal governmental plans, 99,667 notices need to be produced annually in 2012, 2013 and 2014. At 30 seconds per notice, we estimate the total annual burden hours to be 831 hours in each of 2012, 2013 and 2014.

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.

Estimated Annualized Burden Table for 2012

Forms (If necessary)	**Type of Respondent**	**Number of Respondents**	**Number of Responses**	**Average Burden hours per Response**	**Total Burden Hours**
Form Filing Submission	Issuers	83	83	20 policies, 1 hour each	1660
Form Filing New Submission	Issuers	83	83	3 hour	249
Federal Review State Information	N/A			Burden Exempt	
Certificates Group	Issuers/plans	1,400	34,900,000	5 minutes	2,908,333
Certificates-Individual	Issuers	1,000	2,929,759	17.11 minutes	835,517
General Preexisting Notice	Issuers/plans	700	400,000	Already in plan materials	
Individual Preexisting Notice	Issuers/plans	700	7,080 is a subset of 400,000 above	2 minutes	236
Special Enrollment	NFG Plans	1,400	1,600,000	Burden Exempt	
Impaired Financial Capability	N/A				

Forms (If necessary)	Type of Respondent	Number of Respondents	Number of Responses	Average Burden hours per Response	Total Burden Hours
Guaranteed Availability	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)	20 policies, 1 hour each	
Guaranteed Availability New Submission	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)	3 hours	
Recordkeeping non HIPAA Eligibles	Issuers	1,000	50,000	0.33	16,667
Intent to Discontinue	N/A				
Guaranteed Renewability	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)		
Small Employers - Guaranteed Availability	Issuers	1,200	1,200	2 hours	2,400
CMS Coverage for EHB Package	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)		
Opt-Out to CMS (prepare notice)	NFG Plans	650	650	0.25	163
Opt-Out Notice Preparation and Dissemination	NFG Plans	650	No Public Burden		
Opt-Out Notice to Members	NFG Plans	650	99,667	30 seconds	831
Total		9,516	39,981,442		3,766,056

Estimated Annualized Burden Table for 2013

Forms (If necessary)	**Type of Respondent**	**Number of Respondents**	**Number of Responses**	**Average Burden hours per Response**	**Total Burden Hours**
Form Filing Submission	Issuers	83	83	20 policies, 1 hour each	1660
Form Filing (New) Submission	Issuers	83	83	3 hour	249
Federal Review State Information	N/A			Burden Exempt	
Certificates-Group	Issuers/plans	1,400	34,900,000	5 minutes	2,908,333
Certificates-Individual	Issuers	1,000	2,929,759	17.11 minutes	835,517
General Preexisting Notice	Issuers/plans	700	400,000	Already in plan materials	
Individual Preexisting Notice	Issuers/plans	700	7,080 is a subset of 400,000 above	2 minutes	236
Special Enrollment	NFG Plans	1,400	1,600,000	Burden Exempt	
Impaired Financial Capability	N/A				
Guaranteed Availability	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)	20 policies, 1 hour each	
Guaranteed Availability (New) Submission	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)	3 hour	
Recordkeeping non HIPAA Eligibles	Issuers	1,000	50,000	0.33	16,667

Forms (If necessary)	Type of Respondent	Number of Respondents	Number of Responses	Average Burden hours per Response	Total Burden Hours
Intent to Discontinue	N/A				
Guaranteed Renewability	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)		
Small Employers - Guaranteed Availability	Issuers	1,200	1,200	2 hours	2,400
CMS Coverage for EHB Package	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)		
Opt-Out to CMS (prepare notice)	NFG Plans	650	650	0.25	163
Opt-Out Notice Preparation and Dissemination	NFG Plans	650	No Public Burden		
Opt-Out Notice to Members	NFG Plans	650	99,667	30 seconds	831
Total		9,516	39,981,442		3,766,056

Estimated Annualized Burden Table for 2014

Forms (If necessary)	**Type of Respondent**	**Number of Respondents**	**Number of Responses**	**Average Burden hours per Response**	**Total Burden Hours**
Form Filing Submission	Issuers	83	83	20 policies, 1 hour each	1660
Form Filing (New) Submission	Issuers	83	83	3 hour	249
Federal Review State Information	N/A			Burden Exempt	
Certificates-Group	Issuers/plans	1,400	34,900,000	5 minutes	2,908,333
Certificates-Individual	Issuers	1,000	2,929,759	17.11 minutes	835,517
Special Enrollment	NFG Plans	1,400	1,600,000	Burden Exempt	
Impaired Financial Capability	N/A				
Guaranteed Availability	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)	20 policies, 1 hour each	
Guaranteed Availability (New) Submission	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)	3 hour	
Intent to Discontinue	N/A				
Guaranteed Renewability	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)		

Forms (If necessary)	Type of Respondent	Number of Respondents	Number of Responses	Average Burden hours per Response	Total Burden Hours
Small Employers - Guaranteed Availability	Issuers	1,200	1,200	2 hours	2,400
CMS Coverage for EHB Package	Issuers	83 (accounted for in Form Filing Submission)	83 (accounted for in Form Filing Submission)		
Opt-Out to CMS (prepare notice)	NFG Plans	650	650	0.25	163
Opt-Out Notice Preparation and Dissemination	NFG Plans	650	No Public Burden		
Opt-Out Notice to Members	NFG Plans	650	99,667	30 seconds	831
Total		7,116	39,531,442		3,749,153

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 Ac; 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. 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 form filings is not anticipated to exceed $3.7 million per year. The contract will be managed by staff in the Washington, D.C. area at the GS-13 level. Based on the 2012 GS pay schedule, a GS-13, Step 1 earns $89,033 annually. We estimate that managing this contract is not anticipated to exceed 1,040 hours per year.

15. Changes to Burden

There are program burden changes in this ICR. As indicated in the Background section, this revised burden is a result of new statutory requirements under title XXVII of the PHS Act. With respect to health insurance issuer burden in a state in which CMS is enforcing any of the requirements under title XXVII of the PHS Act, we revised the burden estimate to reflect that CMS does not know which or how many states CMS will be enforcing these requirements. We estimate the burden for an average state. Accordingly, direct enforcement by CMS in more than one state would be a multiple of that burden. The burden estimate for CMS to enforce in an average state is 1,909 burden hours and an equivalent cost of about $58,549. This estimate is made assuming health insurance issuers will need to submit form filings, approximately 20 forms per company and one hour to produce each form, and in the event of a material change to a policy form, three hours annually. This revision reduces the previous burden estimate from 8,050 burden hours to 1,909 burden hours (reducing the burden hours by 6,141 hours).

For the group market, we reduced the burden by 236 hours in 2014 to account for the changes to the statutory requirements for preexisting condition exclusions.

For the individual market, we reduced the burden by 4,200 burden hours to account for the changes to the individual market requirements for state alternative mechanism. In addition, we reduced the burden by 16,667 hours in 2014 to account for the changes to the requirements. Finally, we increased all labor costs from $18.27 to $30.67 to account for inflation.

There are no new 2012 PRA burden hours:

For 2012 and 2013:
3,776,397 hours (2009 hours) – 10,341 hours = 3,766,056 (2012 and 2013 burden hours).

For 2014:
3,776,397 hours (2009 hours) – (10,341 hours + 16,903 hours) = 3,749,153 (2014 burden hours).

16. Publication/Tabulation Dates

There are no publication or tabulation dates associated with these ICRs.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date because the requirements as amended into the Public Health Service Act do not expire.

18. Certification Statement

There are no exceptions to the certification and other notice requirements.

ATTACHMENT: MODEL HIPAA EXEMPTION ELECTION AND MODEL NOTICE TO ENROLLEES IN A SELF-FUNDED NONFEDERAL GOVERNMENTAL GROUP HEALTH PLAN