Supporting Statement for Information Collection Requirements Referenced in HIPAA title I for the Group Market, Supporting Regulations at 45 CFR 146 (146.111, 146.115, 146.117, 146.150, 146.152, 146.160, and 146.180) Forms and Instructions
(CMS-R-206)

A. Background

The provisions of title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are designed to make it easier for people to get access to health care coverage and to reduce the limitations that can be put on the coverage. The title I provisions are divided into group and individual market protections. The group provisions apply to employment-related group health plans and to the issuers who sell insurance in connection with group health plans. For HIPAA purposes, all other health insurance is sold in the individual market. These regulations that are the subject of this submission implement the group market rules under HIPAA as they apply to non-Federal governmental group health plans and group health insurance issuers. A separate regulation implements the individual market provisions.

In addition to the issuance of certificates of creditable coverage, the notices of preexisting condition exclusion and the notices of special enrollment rights (the portability provisions shared with the Departments of Labor and Treasury, which they administer with regard to private group health plans and church plans), the group market regulations contain a number of CMS-only information collection requirements (ICRs) located at 45 CFR 146 (146.111, 146.115, 146.117, 146.150, 146.152, 146.160, and 146.180). Some of the CMS-only ICRs relate to state review of issuers' filings of group market products or similar Federal review in cases in which a state is not enforcing a HIPAA group market provision. Still others pertain to self-funded state and local governmental plans' opting out of HIPAA requirements with respect to their employees.

Under HIPAA, states are held directly responsible for enforcing the paperwork requirements associated with the Federal requirements. However, states generally take the view that they cannot directly enforce Federal law. They must first incorporate it into state law or regulations in order to enforce it. Section 2722(a)(2) of the Public Health Service Act (PHS Act) as amended by HIPAA provides that, in the case of a determination by CMS that a state has failed to substantially adopt or enforce a provision (or provisions) of these group market rules with respect to health insurance issuers, CMS shall enforce such provision or provisions in the state insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans in the state.

In §150.203 of the regulations, we provided for two possibilities. The first is a situation in which the state elects not to enforce the Federal requirements and voluntarily invites CMS in to enforce the Federal provision or provisions directly. In this case, the state may cooperate with CMS in enforcing the Federal law, using its authority to enforce contract provisions of insurance policies that have been amended to comply with HIPAA. The second situation involves CMS's rendering of a formal determination, in accordance with Federal regulations, that a state has failed to substantially enforce one or more provisions of the group market rules. In this second situation, cooperation of the state cannot be assumed. Thus, we must prepare for several eventualities. The information collection request associated with the group market rules were modified through the 1999 PRA package to permit two party collections between the Federal government and issuers in varying enforcement situations ranging from cooperative Federal/state enforcement of virtually all group and individual market provisions, to patchwork enforcement of selected provisions with or without the cooperation of the state.

Several states have not fully adopted the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA) (42 USC 300gg-4 and 42 USC 300gg-51) and/or the Women's Health and Cancer Rights Act of 1998 (WHCRA) (42 USC 300gg-4 et seq.). Both of these statutes pertain to individual and group coverage. In the absence of state oversight, the Federal government enforces these amendments to HIPAA directly. Issuers in Wisconsin have had to submit to CMS documentation demonstrating compliance with both amendments. Issuers in Colorado and Massachusetts do the same for WHCRA alone. Since issuers in these states must file the same documentation with the state insurance departments (with their general form filings), there is no additional burden imposed by Federal HIPAA enforcement. They need only photocopy the materials compiled for the states and mail the copies to CMS.

B. Justification

1. Need and Legal Basis

All but two of the ICRs in the group market regulations are supported by statute. The first exception is described below in B.1 (b) Notice to All Participants and Notice to an Individual of Preexisting Condition Exclusion. 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 adversely impacted. The second is described in B.1(c) Notice to Participants Regarding Special Enrollment Periods. It 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. Otherwise, the statutory and regulatory basis for each of these ICRs is identified below along with a brief description of the requirement.

a. Certificates and Disclosure of Prior Coverage

Regulatory basis: 45 CFR 146.115 Certification and Disclosure of Previous Coverage
Statutory basis: Section 2701(e) 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 is accomplished primarily through the issuance of certificates of prior coverage by plans or issuers that provide group 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. Consistent with the final group market portability regulation, published December 30, 2004, the certificate must include an educational statement regarding HIPAA portability rights. The statement explains restrictions on preexisting condition exclusions that an issuer may impose, special enrollment rights, prohibitions against discrimination based on health factors, rights to individual health coverage under certain circumstances, the fact that state law may require more protections and where to obtain more information.

Model educational language is provided in the new model certificate. This eliminates the burden on issuers of developing language to satisfy this requirement. Use of the new 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) of the regulations. 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 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 final regulations, in order to satisfy the requirements of 45 CFR 146.115(a)(3)(ii).

The final regulations retain the methods in the April 1997 interim rules for counting creditable coverage, that is, the standard method and the alternative method. Plans and issuers may use the model disclosure form in reporting specific benefits to issuers that use the alternative method of crediting coverage for: mental health, substance abuse, prescription drugs, dental care and vision care. The prior entity is required to identify to the requesting entity the categories of benefits with respect to which the requesting entity is seeking to apply the alternative method of counting coverage, and the requesting entity may identify specific information that the requesting entity reasonably needs in order to determine the individual's creditable coverage with respect to any such category.

When CMS has been invited in to enforce all Federal HIPAA requirements in a state (as in Missouri), CMS will initially monitor issuers' non-compliance with the certification process through complaints. However, if a complaint or allegation is identified and CMS suspects there is widespread non-compliance on the part of issuers, CMS will require issuers to submit sample certificates. In addition, when CMS determines that a state is failing to substantially enforce the certification requirements through its complaint process and/or policy review and that Federal enforcement of these provisions is necessary, CMS will require issuers to submit sample certificates. ICRs obtained pursuant to enforcement actions (i.e., audits, investigations) are exempt from the PRA as described under 5 CFR 1320.4(a)(2).

b. Notice to All Participants and Notice to an Individual 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 know where they stand with respect to the imposition of preexisting condition exclusion on them. To ensure compliance with this regulatory authority, CMS or states will require issuers to submit sample notices and/or deal with noncompliance on complaint-based audits.

This set of ICRs concerns the disclosure requirements on those issuers of group health coverage that use preexisting condition exclusion provisions. It has two components: first, a notice to all participants at the time of enrollment stating the terms of the plan's preexisting condition exclusion provisions, the participant's right to demonstrate creditable coverage, and that the plan or issuer will assist in securing a certificate if necessary; and second, if an issuer's preexisting condition exclusion is not completely offset by prior creditable coverage, notice by the issuer of its determination that an exclusion period applies to an individual, and the length of that exclusion. Model language that issuers may use to notify participants about preexisting condition exclusions was included in the 2004 final regulations.

If a state fails to, or chooses not to, substantially enforce these notification requirements with respect to issuers who have contracted with plans to provide them and Federal enforcement of this section is necessary, CMS will monitor issuers' non-compliance through up-front submissions of sample notices to ensure that adequate notification of rights is being provided to all plan participants and beneficiaries. We believe that it is necessary for CMS to ensure through up-front submission of notices that individuals will receive accurate notices of eligibility and coverage rights because individuals would not otherwise be aware of their rights. We will also investigate complaints relating to the failure to deliver accurate notices. Enforcement actions based on complaints are exempt from the PRA as described under 5 CFR 1320.4(a)(2).

c. Notice to Participants Regarding Special Enrollment Periods

Regulatory basis: 45 CFR 146.117 Special Enrollment Periods

This section in the 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 in the regulation at 146.117(c).

d. Notice to State or Federal Government 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

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 only required to report to the applicable state authority if they are discontinuing coverage in the small group market. For the one state in which the Federal government is enforcing this provision in the absence of state authority, issuers report the required information to CMS rather than to the state.

e. State or 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
Statutory basis: Section 2711(a) and (b) of the PHS Act

Under HIPAA, states must ensure guaranteed availability of all products to all small group market employers. In order to ensure compliance with section 2711 of the statute, states will 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 are guaranteed availability of coverage in the small group market.

In states in which CMS is directly enforcing the small group market guaranteed

availability requirement (currently Missouri), CMS will collect this information directly as part of its enforcement activities. The following chart identifies the various materials that CMS will need to review in order to determine compliance with the all products guarantee required by §146.150. These materials will also be reviewed to determine compliance with all other group market requirements, including, but not limited to, those listed under other sections of this PRA package, as being enforced through the form filing process (in which case we will refer back to this table) as well as with the common rules for both the individual and group markets, as set forth in Part 144 (which includes the common definitions in 144. §103). We are therefore listing all these materials together here because we will verify that all materials have been submitted at reception of a policy form filing.

Materials Required for Submission of Policies for Review by CMS
For HIPAA Compliance In the Group Market

Requested Material	Small Group Market	Large Group Market	Does the State Already Collect This Information on a Routine Basis?
Issuer name and address	Yes	Yes	Yes
Name, address, and telephone number where complaints are to be sent	Yes	Yes	Yes
Clear indication of the market for which the following materials are being submitted (i.e., individual, small or large group market)	Yes	Yes	Yes/No (depends on state authority)
Policy forms being actively marketed or intended for sale in the group market	Yes	Yes	Yes
Application and enrollment forms, health questionnaires used with all of the above; service and enrollment areas, if applicable	Yes	Yes	Yes
Marketing materials used with all of the above	Yes	No	Yes/No (depends on state authority)
Examples of group market notices (such as those regarding preexisting	Yes	Yes	Yes/No

conditions, affiliation periods, use of alternative method of crediting coverage) the issuer has contracted with plans to provide **or** a statement that the issuer has not contracted to provide such notices			(depends on state authority)
Employer contribution and employee participation rules applied to all actively marketed group policies	Yes	Yes	Yes/No (depends on state authority)
Explanation of pooling practices used, or to be used, to spread risk across various policy forms	Yes	No	Yes/No (depends on state authority)

Attachment 1 contains the letters of request used by Federal regulators to obtain materials for submission of policies in the group market. Attachment 2 contains the model opt-out election and plan member notification.

f. Notice to State or Federal Government 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

In this section issuers are required to report to the state or Federal government, as appropriate, if they are discontinuing a particular type of coverage or discontinuing all coverage. States already require such notice and in Missouri it is estimated that fewer than 10 issuers will be subject to it annually. It is therefore not subject to PRA requirements.

g. State or 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
Statutory basis: Section 2712(a) 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.

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

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. In Missouri where CMS is enforcing the all products guarantee, we will ensure compliance with these disclosure requirements by reviewing on an up front basis all marketing materials, application forms, and related materials listed in the table above.

i. Notice to Federal Government of Non-Federal Governmental Plan Opt-Out

Regulatory basis: 45 CFR 146.180 Treatment of Non-Federal Governmental Plans
Statutory basis: Section 2721(b)(2)(A) 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**.**

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, under146.180, 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).

j. 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 2721(b)(2)(C) 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 also attachment 2).

2. Information Users

Plan participants and their dependents need this information to take advantage of the rights they have under HIPAA (ICRs a, b, c, and j). States and the Federal government need the information supplied by plans and issuers to properly perform their regulatory functions under HIPAA and/or existing state law (ICRs d, e, f, g and h).

3. Use of Information Technology

Issuers are expected to use their data processing systems to generate the certificates and other notices to plan participants. Telephonic interchange of certificate information is permitted, in lieu of a certificate, if all parties agree.

4. Duplication of Efforts

Based on practices to date, the ICRs outlined in this supporting statement are the only viable and least burdensome way of monitoring market activity and ensuring compliance with these statutory and regulatory requirements. In addition, the need for these ICRs has been supported by states that have been implementing these provisions to date.

5. Small Businesses

N/A. These ICRs do not affect small businesses, because CMS (unlike the Department of Labor or Treasury) only regulates health insurance issuers, and health plans sponsored by states and local governments, not health plans sponsored by small employers.

6. Less Frequent Collection

Certificates must be issued when an individual loses coverage under a plan, and upon requests made no later than 24 months after the individual loses coverage. There is no method to reduce the frequency that would not result in noncompliance with the requirements. If certificates are not generated as required and the state does not substantially enforce these HIPAA requirements with respect to health insurance issuers, the Federal government would have to enforce these provisions.

7. Special Circumstances

N/A. There are no special circumstances.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on _____.

In the course of developing the Final Regulations for Health Coverage Portability: Final Rule, the Departments revised the administrative burden estimates, based on consultation with plans and issuers affected by them. Also, states have shared their experiences with CMS in an effort to enhance the quality of the information gathered. As a result, the ICRs referenced in the table under B.1.e. were determined to be the minimal data requirements necessary to ensure compliance with statutory requirements in the least burdensome manner.

9. Payments/Gifts To Respondents

No payments or gifts are associated with these ICRs.

10. Confidentiality

These ICRs raise no confidentiality concerns. The data provided relate to periods of coverage, not medical conditions that might or might not be paid for by the health coverage. Also, information contained in these ICRs that identifies any individual is provided to that individual, not to a third party.

11. Sensitive Questions

These ICRs involve no sensitive questions.

12. Burden Estimate (Hours & Wages)

Total burden hours are identified below for each of the ICRs covered by the group market regulations. See Table below for a summary of burden hours and costs per ICR. These reflect updates the Departments conducted at the time of the publication of the final regulation.

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 $53,135,250. The amount of burden per respondent has not changed; however, the total burden hours and total cost estimates have been adjusted due to a mathematical correction.

The 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 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. This time estimate is based on discussions with industry representatives. 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
When CMS is enforcing the certificate of creditable coverage requirements in a state, we will enforce compliance on a complaint basis or through a focused audit/investigation process, which is exempt from the PRA as described above.

State Burden--Compliance Review
When states are enforcing the certificate of creditable coverage requirements, they will enforce compliance on a complaint basis or through focused audit/investigation process, which is exempt from the PRA as described above.

b. Notice to All Participants and Notice to an Individual of Preexisting Condition Exclusion

Issuer Burden--Notice Issuance
This ICR has two components: (1) a general notice to all participants at the time of 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.

(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 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 2009; 400,000 notices in 2010; and 400,000 notices in 2011. 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, or $89, 804 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

When CMS is enforcing these notification requirements as part of Federal enforcement in a state that has voluntarily invited CMS to take over enforcement of all or nearly all group market provisions (currently Missouri), we will enforce compliance through review of policies and supporting materials. The burden estimate associated with the policy review function is captured below under section B.12. e., "State or Federal Review of Policy Forms to Ensure Guaranteed Availability.". Federal enforcement of this notification requirement, on a patchwork basis, in states failing to enforce only this preexisting condition exclusion notice requirement or only a few other requirements will be done 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).

State Burden--Compliance Review

When states enforce these notification requirements through existing state laws and regulations, the burden associated with this ICR is exempt from the PRA, described in 5 CFR 1320.3(b)(3). When states are enforcing these notification requirements on a complaint basis or through a focused audit/investigation process, these ICRs are also exempt from the PRA, as described above.

c. Notice to Participants Regarding Special Enrollment Periods

Issuer Burden--Notice Issuance

Under the 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 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. (This dollar amount is a change from the previous PRA package. The change is due to an error in mathematical calculations. This does not affect the burden estimate.) 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 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.)

State Burden--Compliance Review
Since these notification requirements apply to plans, not to issuers, there is no state compliance review.

d. Notice to State or Federal Government of Impaired Financial Capability

State Burden
Prior to this regulation, this requirement existed under insurance industry practices. We estimate that all state insurance departments, except Missouri's oversee discontinuance of insurance products in their state by requiring some type of notice of impaired financial capacity as a normal business practice in conjunction with their solvency regulations. Therefore, the burden associated with these ICRs is exempt from the PRA under 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(b)(3).

Issuer Burden--Federal Compliance Review
When CMS is enforcing this requirement in a state in the absence of state authority, we will require issuers to report impaired financial capacity directly to CMS. We estimate that issuers in one state will be required to report directly to CMS if they encounter financial difficulties. Since Missouri, currently under Federal enforcement, closely

monitors 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. Missouri follows NAIC procedures and has had an extremely low incidence of issuer insolvency. 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. State or Federal Review of Policy Forms to Ensure Guaranteed Availability

State Burden--Policy Review

(1) Under HIPAA, states must review policies during their oversight process to make sure there is a guaranteed availability clause in each policy. All states (except Missouri) already require guaranteed availability as normal business practice. If the state identifies a violation and has to take some action, we believe that each state will be required to initiate fewer than 10 administrative actions on an annual basis against specific individuals or entities who failed to implement the Federal guarantee availability requirements.

Issuer Burden--Federal Compliance Review

(2) Currently CMS is enforcing the guaranteed availability, guaranteed renewabiltiy and disclosure requirements in Missouri alone. We have calculated our estimates based on the 350 issuers that actually have filed with CMS for approval in that state. We estimate that these issuers have filed an average of 20 policies, each requiring one-hour's burden to prepare the necessary documentation for a triennial comprehensive resubmission to CMS. The total burden associated with these requirements (7,000 hours) is based on the assumption that issuers are required to resubmit all products being actively marketed in the group market.

(3) After the comprehensive resubmission 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 350 issuers will each require on average three hours for this activity annually. The total burden is 1,050 hours.

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

State Burden

This requirement exists in the absence of this regulation under current insurance industry practices. We estimate that all but one of the state insurance departments oversee

discontinuance of insurance products in their state by requiring some type of notice of impaired financial capacity as a normal business practice in conjunction with their solvency regulations. Therefore, the burden associated with these ICRs is exempt from the PRA under 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(b)(3).

Issuer Burden--Federal Compliance Review
When CMS is enforcing this requirement in a state in the absence of state authority, we will require issuers to report product discontinuance or market abandonment directly to CMS. We estimate that issuers in one state (Missouri) 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. We estimate therefore 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. State and Federal Review of Policy Forms to Ensure Guaranteed Renewability

State Burden
Under HIPAA, states must review policies during their oversight process to make sure there is a guaranteed renewability clause in each policy. All states but Missouri currently do so. If the state identifies a violation and a state has to take some action, we believe that each state will be required to initiate fewer than 10 administrative actions on an annual basis against specific individuals or entities that failed to implement the Federal guaranteed renewability requirements.

Issuer Burden--Federal Compliance Review
When 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 function is captured above under section B.12.g. "/State and Federal Review of Policy Forms to Ensure Guaranteed Renewability."

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.

State Burden

Under HIPAA, states must ensure that issuers' materials and related policy information provide full disclosure of the benefits and premiums associated with all products the issuer markets in the small group market, as well as other information. All states, except Missouri, currently require submission of marketing materials and related policy information to ensure issuer compliance with this disclosure requirement under state law and regulations. Therefore, the burden associated with this requirement is exempt from the PRA, as outlined in 5 CFR 1320.3(b)(2) and (3).

Issuer Burden--Federal Compliance Review

When 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 captured above under section B.12.e., "State or Federal Review of Policy Forms to Ensure Guaranteed Availability."

i. Notice to Federal Government of 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 attachment 2 and forward it to CMS. 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 650 plans in our database for the opt-out provision.

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.

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

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

(1) The 650 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 the 650 non-Federal governmental plans, 99,667 notices need to be produced annually in 2009, 2010 and 2011. At 30 seconds per notice, we estimate the total annual burden hours to be 831 hours in 2009, 2010 and 2011.

Plan Burden--Federal Compliance Review
CMS will enforce compliance with the opt-out notification to enrollee's requirement on a complaint basis or through a focused audit/investigation process, which is exempt from the PRA as described above.

13. Capital Costs
Because this legislation has been in effect for many plans since 1997, there are no capital costs. No entities have to purchase computers, software or equipment in order to comply with the ICRs.

14. Cost to Federal Government
These ICRs involve primarily third party information exchanges between plans/issuers and individuals covered under the plan/issuers' policies and between issuers and states enforcing HIPAA standards. Generally, the Federal government becomes involved only if a state either chooses not to enforce these provisions and invites CMS to enforce these provisions within its borders or fails to substantially enforce issuer compliance with these requirements. CMS is currently enforcing the group market requirements only in the State of Missouri.

The previous 2006 PRA package had an additional Federal costs as $208,000 for a contractor to conduct a market review. CMS does not have the funding to contract for a market review and all reviews will be conducted in-house. Therefore, there will be no additional cost to the Federal government.

15. Changes to Burden
There are no program burden changes. The change is burden is due to a correction in the mathematical calculations for item 12a.

16. Publication/Tabulation Dates

A 60-day Federal Register notice was published on April 19, 2009. No comments were received.
N/A. There are no publication or tabulation dates associated with these ICRs.

17. Expiration Date
There are no forms on which to place an expiration date.

18. Certification Statement
N/A. There are no exceptions to the certification and other notice requirements.

C. Collection of Information Employing Statistical Methods
N/A.

ATTACHMENT 1: LETTERS OF REQUEST

ATTACHMENT 2: MODEL HIPAA EXEMPTION ELECTION AND MODEL NOTICE TO ENROLLEES IN A SELF-FUNDED NONFEDERAL GOVERNMENTAL GROUP HEALTH PLAN