Supporting Statement for Information Collection Requirements
Referenced in HIPAA title 1 for the Individual Market, Supporting Regulations at 45 CFR 148 (148.120, 148.122, 148.124, 148.126, and 148.128), Forms and Instructions
(CMS-R-205)

A. Background

The provisions of title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) amend the Public Health Service Act (PHS Act) and are designed to make it easier for people to get access to health care coverage; to reduce the limitations that can be put on the coverage; and to make it more difficult for issuers to terminate the coverage. 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. This Paperwork Reduction Act (PRA) submission reflects the requirements in the individual market rules under HIPAA.

We believe that the individual health insurance market provisions of HIPAA recognize that states play the primary role in the regulation of insurance and afford the states great flexibility in implementing the reforms required by the statute. In the event that a state substantially fails to enforce Federal requirements, the statute provides enforcement authority to the Department of Health and Human Services (HHS); however, the primary authority clearly rests with the states. HHS (by delegation to the Centers for Medicare & Medicaid Services (CMS)) will, however, fulfill its statutory responsibility and regulatory authority to intervene by directly regulating the individual market in a state that either chooses not to enforce or fails to enforce the individual market provisions of HIPAA, or doesn't adopt an appropriate alternative mechanism to guarantee the availability of individual coverage to persons meeting the criteria specified in HIPAA.

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 mandate 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. Thereafter, for purposes of this submission, the territories will be included in the category of "states".

When CMS enforces the Federal fallback requirements directly, issuers are required to submit necessary documentation to the Federal government to demonstrate their compliance with

HIPAA requirements. This information includes documentation that states currently review or would have reviewed to demonstrate compliance with HIPAA if they had enacted the Federal fallback provisions and were enforcing these requirements themselves. In 2006, CMS was enforcing the individual market provisions only in Missouri. In 2008, Missouri adopted an alternative mechanism. CMS, therefore, is currently not enforcing the individual market provisions in any states.

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 the NMHPA and WHCRA 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, 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

The statute requires all of the information collection requirements in the individual market. The statutory and regulatory basis for each of these information collection requirements is identified below along with a brief description of the requirement.

148.120 Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage.

Statutory basis: Section 2741 of the PHS Act

Section 2741 specifies the Federal fallback requirements. This section requires all issuers in the individual market to offer guarantee issue all of their products to eligible individuals with no preexisting condition exclusion period. However, states may instead decide to provide for guaranteed availability of a choice of coverage to eligible individuals through an alternative mechanism provided for under section 2744. In that case, issuers in the state that are not involved with implementation of the mechanism are absolved of these obligations under section 2741.

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.

If a state chooses to enforce the Federal fallback requirements, the provisions of 148.120 apply, and are enforced by the state under state law. Once the state has adopted HIPAA requirements into state law and regulations, the burden associated with these requirements is exempt from the PRA as described under 5 CFR 1320.3(b)(3). Where states have chosen to implement an alternative mechanism under 148.128, the burden associated with the states' enforcement of their alternative mechanism provisions is exempt from the PRA (See 148.128). This is due to the fact that states have now implemented the guaranteed availability requirements through their mechanisms under state laws and regulations.

If a state implements neither an alternative mechanism nor the Federal fallback requirements, CMS will implement the Federal fallback provisions in the state and will enforce those requirements using the penalty provisions in 45 CFR 150.301. Under Federal enforcement of the record keeping and information collection requirements associated with 148.120, many issuers selling in the individual market will choose the alternative coverage option as a means of restricting their offerings from the all-products guarantee required by 148.120(a)(1) either to their two most popular policies, based on premium volume, or to two representative policies with a higher and a lower actuarial value, as permitted by 148.120(c)(2) and (3) of the regulations.

In the 2006 PRA package, CMS accounted for the 11,463 burden hours associated with enforcing the individual market provisions in Missouri. The 2006 burden estimate was based on data for 350 issuers in Missouri. As of 7/1/2008 Missouri adopted a state alternative mechanism and CMS no longer enforces the individual market provisions in Missouri. As stated above, where states have chosen to implement an alternative mechanism under 148.128, the burden associated with the states' enforcement of their alternative mechanism provisions is exempt from the PRA (See 148.128). Therefore, due to the program change we are no longer counting the 11,463 burden hours for Missouri. At this point in time, CMS is not enforcing the individual market provisions in any state.

148.122 Guaranteed renewability of individual health insurance coverage.
Statutory basis: Section 2742 of the PHS Act

This section requires 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 currently require guaranteed renewability as a normal business practice. Therefore, the burden associated with these information collection requirements is exempt from the PRA.

In this section of the regulations, issuers are also required to report if they are discontinuing a particular type of coverage or discontinuing all coverage. This requirement exists in the absence of this regulation because under current insurance practices, state insurance departments perform policy form reviews and oversee the discontinuance of insurance products in their state as a normal business practice. Therefore, the burden associated with this information collection requirement is exempt from the PRA under 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(b)(3).

148.124 Certification and disclosure of coverage.
Statutory basis: Section 2743 of the PHS Act

Section 148.124 specifies that an issuer in the individual market must provide a written certificate of creditable coverage, and, if required, make certain other disclosures regarding an individual's coverage under an individual policy. In general, the certification and disclosure requirements are similar to the relevant provisions of 146.115 that apply to health insurance coverage offered by issuers in the group market. The certificates from issuers in the individual market and other disclosures of information are intended to enable individuals to avoid or reduce preexisting condition exclusions under subsequent group health insurance coverage the individual may obtain.

Individuals have the right to receive a certificate automatically when they lose coverage under an individual policy. A certificate must also be provided upon a request by, or on behalf of, an individual during the period not later than 24 months after coverage ceases. The certificate must be provided at the earliest time that an issuer, acting in a reasonable and prompt fashion, can provide the certificate. The certificate must also be provided consistent with state law.

An issuer of an individual policy is required, to the same extent as an issuer of insurance in the group market, to prepare certificates with respect to the coverage of any of the individual's dependents that are covered under the individual policy.

We anticipate that 1,000 issuers will generate, on an annual basis, 2,929,759 individual market certificates. We are assuming that the majority of certificates issued in the individual market will require issuers to find out the application date since many individuals will have fewer than 18 months of creditable coverage with that issuer.

The ranges of time estimates, with industry averages, as shown in the table below, are based on discussions with industry representatives. We believe that as a routine business practice, the issuers' administrative staffs have the necessary information readily available to generate the required certificates. In addition, we have determined that the majority of issuers have or will have the capability to automatically computer generate and disseminate the necessary certification when appropriate.

Year	Total Respondents	Total Responses	Average Time per Response (rounded average)	Average Total Burden Hours	Cost per Hour	Average Total Cost
2009	1,000	2,929,759	17.11 minutes	835,517 hours	$18.27	$15,264,896
2010	1,000	2,929,759	17.11 minutes	835,517 hours	$18.27	$15,264,896
2011	1,000	2,929,759	17.11 minutes	835,517 hours	$18.27	$15,264,896

148.126 Determination of an eligible individual.
This section requires issuers to determine whether individuals are eligible individuals.

In this section, issuers must also maintain records for those individuals whom they determine are not HIPAA eligible individuals. In the event of a market conduct review, this allows the issuer to demonstrate compliance. We estimate that records for 50 individuals for each of 1,000 issuers, or 50,000 records will be maintained each year. At 20 minutes per record, this represents a total annual burden of 16,667 hours.

Federal enforcement of the requirement to determine whether individuals are eligible individuals will be accomplished chiefly through inspection of application forms and marketing materials to ensure that eligible individuals are being informed of their right to purchase a policy and assisted in demonstrating their eligibility for this status. These marketing materials and application forms are already being collected, for purposes of enforcing guaranteed availability, under 148.120.

148.128 State flexibility in individual market reforms--alternative mechanisms.
Statutory basis: Section 2744 of the PHS Act.

Currently, 42 states have alternative mechanisms. Any additional facts or opinions obtained or solicited by CMS from a state as follow-up regarding the state's implementation of its alternative mechanism is exempt from the PRA. Eight states are implementing the Federal fallback requirements themselves; therefore, the maximum number of states that would consider revising their plans (i.e., decide to submit an alternative mechanism instead of continuing to enforce the Federal fallback provisions) is eight.

Every three years, the statute requires all states doing alternative mechanisms to resubmit their

alternative mechanisms for continued approval. Based on communication with states, for the next review cycle in 2009, we estimate that 42 states will submit or resubmit alternative mechanism proposals. The number of staff hours per state submission has been calculated at 100 for those states that have submitted their documentation in previous review cycles.

2. Information Users

Individuals and their dependents need certificates of creditable coverage to take advantage of the rights they have under HIPAA. States (and CMS, where necessary) need the information supplied by issuers to properly perform their regulatory functions under HIPAA and/or existing state law.

3. Use of Information Technology

Issuers are expected to use their data processing systems to generate the certificates of creditable coverage. If all parties agree, telephonic interchange of certificate information is permitted, in lieu of a certificate.

4. Duplication of Efforts

Not applicable. There are no other current Federal information collection requirements that can be used to meet these requirements. Where we have identified information collection requirements redundant to state requirements, we have worked to minimize Federal reporting requirements.

5. Small Businesses

Not applicable. The information collection requirements do not impact small businesses.

6. Less Frequent Collection

The information collection requirements are required by statute and therefore cannot be reduced.

7. Special Circumstances

None.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on April 10, 2009, no comments were received. There has not been additional outside consultation since the last approval.

9. Payments/Gifts to Respondents

Not applicable. There are no payments or gifts associated with these information collection requirements.

10. Confidentiality

Not applicable. The terms of the collection provide no confidentiality requirements.

11. Sensitive Questions

Not applicable. The information submitted for the state alternative mechanisms is of a governmental, public policy nature, and does not include any personal information about any individuals.

12. Burden Estimates (Hours & Wages – see attached table)

- Guaranteed Renewability (148.122)
  Item 1 of the attached table: Reviewing new policies for guaranteed renewability clause. All other states now review for this under normal business practice. It is, therefore, exempt from PRA requirements under HIPAA.

- Certificates of Coverage (148.124)
  Item 2 of the attached table: Issue certificates to individuals. (See chart above.) The anticipated maximum annual burden hours for 2009, 2010 and 2011 is 835,517.

- Determination of an Eligible Individual (148.126)
  Item 3 of the attached table: Maintaining records for those individuals issuers determine are not HIPAA eligible. 1,000 issuers x 50 individuals on average x 20 minutes=16,667 hours.

- State Alternative Mechanism (SAM) (148.128)
  Item 4 of the attached table: Alternative mechanism proposals have been completed for the 2006 cycle. Only the burden associated with state enforcement of an alternative mechanism under state laws and regulations is exempt from the PRA, as stated above. For the next review cycle in 2009, we estimate that 42 states will submit alternative mechanism proposals with each submission taking an average of 100 hours for a total burden of 4,200 hours.

  The burden estimate has been modified due to a program change. Since the 2006 PRA

package, Missouri and North Carolina adopted a SAM and Washington State no longer uses a SAM. Washington is now a federal fallback state. For 2006, it was estimated that 41 states would take 100 hours each to complete their SAM plus Missouri would take 400 hours to complete their documentation for a total of 4,500 hours. In the current PRA package, CMS estimates that 42 states will take 100 hours each to complete their SAM for a total of 4,200 hours. This is a program change (decrease) of 300 hours.

Labor costs have been calculated at $18.27 per burden hour in conformity with industry estimates.

13. Capital Costs

There are no capital costs associated with this information collection.

14. Cost to Federal Government

Federal costs-- $558,054 (for 3 year period), plus salaries. Of this total, $556,200 is for consultants and $1,854 for travel. The allocation for the individual market is half, or $279,027.

15. Changes to Burden

The burden estimate has been modified to take into account two factors:

(1) The program burden adjustment (decrease) of 11,463 hours detailed in the last paragraph of #1 (Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage, 45 CFR Section 148.120). In summary, Missouri adopted a state alternative mechanism, therefore, CMS no longer enforces the individual market provisions in Missouri.
(2) The program burden adjustment (decrease) of 300 hours described in the last paragraph of #12 (SAM, 45 CFR Section 148.128) stated above. In summary, Missouri and North Carolina adopted a SAM. Washington State no longer uses a SAM and is a federal fallback state. CMS estimates that 42 states will take 100 hours each to complete their SAM for a total of 4,200 burden hours. Previously it was estimated that 41 states would take 100 hours each to complete their SAMs and Missouri would take 400 hours to complete their documentation for a total of 4,500 hours.

The 2009 PRA burden hours are 856,384 (868,147 (2006 hours) – 11,463 hours – 300 hours = 856,384 hours.

16. Publication/Tabulation Dates

Not applicable. No aggregated results will be published.

17. Expiration Date

We have not included an expiration date, as the forms are used on a continuing basis and would require reprinting based on an expiration date.

18. Certification Statement

There are no exceptions to the "Certification for Paperwork Reduction Act Submissions".

C. Collections of Information Employing Statistical Methods

There are no statistical methods associated with any of these information collection requirements.

ATTACHMENTS: LETTERS OF REQUEST