

**Supporting Statement for HIPAA Nondiscrimination Provisions:  
Notice of Opportunity to Enroll under Certain Circumstances, and Supporting  
Regulations at 45 CFR 146.121  
Agency Form Number CMS-10001**

**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; 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.

Section 2702 of the Public Health Service Act (PHS Act) establishes rules generally prohibiting group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on any health factor of such participants or beneficiaries. Interim final rules implementing the HIPAA nondiscrimination provisions were first published in the Federal Register on April 8, 1997. However, to ensure appropriate guidance was provided to address certain market practices, the Departments of Health and Human Services, Labor and Treasury (Departments) invited comments on particular issues. The preamble to the interim rules further stated that the Departments intended to issue further regulations on the nondiscrimination rules.

On January 8, 2001, we published CMS-2022-IFC (66 FR 1378) in which we solicited comments on the information collection requirements (ICR) including notice of an opportunity to enroll in a group health plan under certain circumstances. Specifically, section 146.121(i)(2) (i) requires that if coverage has been denied to any individual because the sponsor of a self-funded non-Federal governmental plan had elected under 146.180 to exempt the plan from the nondiscrimination requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance with the requirements of this section, the plan must notify the individual that the plan will be coming into compliance with the requirements of this section, afford the individual an opportunity to enroll that continues for at least 30 days, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance with this section (as a matter of administrative convenience, the notice may be disseminated to all employees). We received no comments. The interim final rule was finalized on 12/13/2006, and the associated information collection requirements are approved by OMB through April 30, 2009.

In this Paperwork Reduction Act (PRA) submission, we request an extension of the approval of those requirements which have been approved by The Office of Management and Budget (OMB) under OMB control number 0938-0827.

## **B. Justification**

### **1. Need and Legal Basis**

The statutory and regulatory basis for each of these ICRs is identified below along with a brief description of the requirement.

#### **a. No effect on other laws**

Regulation: CMS-2022-F

Regulatory basis: 45 CFR 146.121 (h), No effect on other laws

Statutory basis: Section 2702(a) and 2702(b) of the PHS Act

Although 146.121 generally does not impose new disclosure obligations on plans and issuers, paragraph (h) states that this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation. Therefore, plan documents (for example, group health insurance policies and certificates of insurance) must be amended if they do not accurately reflect the requirements set forth in this section by the effective date of this section. Under HIPAA, States or the Federal government, as appropriate, reviewed plan documents (for example, group health insurance policies and certificates of insurance) during their oversight process to make sure issuers amended their plan documents to comply with the following requirements set forth in the interim regulations during calendar year 2001:

- Prohibited discrimination in rules for eligibility;
- Specific rule relating to source-of-injury exclusions;
- Prohibited discrimination in premiums or contributions; and
- Nonconfinement and actively-at-work provisions.

#### **b. Notice of Opportunity to Enroll to be Provided to Certain Individuals under the Special Rule for Self-funded Non-Federal Governmental Plans**

Regulatory basis: 45 CFR 146.121(i)(2)(i) Special rule for self-funded non-federal governmental plans exempted under 45 CFR 146.180

Section 146.121(i)(2)(i) requires that if coverage has been denied to any individual because the sponsor of a self-funded non-Federal governmental plan had elected under 146.180 to exempt the plan from the nondiscrimination requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance with the requirements of this section, the plan must notify the individual that the plan will be coming into compliance with the requirements of this section, afford the individual an opportunity to enroll that continues for at least 30 days, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance with this section (as a

matter of administrative convenience, the notice may be disseminated to all employees).

**2. Information Users**

Plan participants and their dependents need this information to understand the new rights they have under HIPAA.

**3. Improved Information Technology**

This collection does not lend itself to improved information technology at this time.

**4. Duplication of Similar Information**

Based on practices to date, this is the least burdensome way of ensuring compliance with these statutory and regulatory requirements.

**5. Small Businesses**

N/A -- Small businesses are not affected.

**6. Less Frequent Collection**

For non-Federal governmental plans that have opted out and elected to opt back in, the necessary plan amendments have most likely coincided with their standard business practices of updating and revising their plan documents for each plan year. The notice generated to inform individuals of their enrollment opportunity in accordance with ICR (b) may be generated in the future, however, depending on the actions of plans currently opting out of the nondiscrimination provisions.

**7. Special Circumstances**

N/A. There are no special circumstances.

**8. Federal Register Notice/Outside Consultation**

The 60-day Federal Register notice for this submission of this information collection request was published on October 3, 2008. A 30-day Federal Register notice was published on December 15, 2008. There were no public comments received. Please see the attached copy.

We consulted extensively with outside groups within the insurance and health care industries as well as with consumer groups during the regulatory development process. The Departments published an Interim Final Rule on April 8, 1997, 62 FR16894, soliciting further comments on the nondiscrimination provisions, and, as noted above, published CMS-2022-IFC on January 8, 2001 with a request for comments on the paperwork requirements. The interim final rule was finalized on 12/13/2006 (71 FR 75014).

**9. Payment/Gift To Respondent**

N/A. No payments or gifts are associated with this request.

## **10. Confidentiality**

N/A. None of the information required to be provided raises any confidentiality concerns.

## **11. Sensitive Questions**

N/A. This request does not involve any sensitive questions.

## **12. Burden Estimate (Total Hours & Wages)**

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. The estimate of burden hours and cost is summarized below:

### Section 146.121: Prohibiting discrimination against participants and beneficiaries based on a health factor.

No effect on other laws: Although this section generally did not impose new disclosure obligations on plans and issuers, this paragraph (h) stated that this section did not affect any other laws, including those that required accurate disclosures and prohibited intentional misrepresentation. Therefore, plan documents (for example, group health insurance policies and certificates of insurance) were required to be amended if they did not accurately reflect the requirements set forth in this section, by the effective date of this section.

The revisions to the plan documents were intended to eliminate provisions that did not comply with the HIPAA nondiscrimination statute and regulations. In particular, it was anticipated that changes were required to the majority of actively-at-work provisions and nonconfinement clauses found in plan documents. The modifications were expected to be made by the effective date of the regulation and the requirements did not impose any on-going burden.

Special rule for self-funded non-federal governmental plans exempted under 45 CFR 146.180: 45 CFR 121 (i)(2)(i) requires that if coverage has been denied to any individual because the sponsor of a self-funded non-Federal governmental plan has elected under 146.180 of this part to exempt the plan from the requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance with the requirements of this section, the plan must notify the individual that the plan will be coming into compliance with the requirements of this section, afford the individual an opportunity to enroll that continues for at least 30 days, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance with this section (as a matter of administrative convenience, the notice may be disseminated to all employees).

The January 8, 2001 interim final rules also included a general transitional rule at 146.121(i)(3)(ii) and (iii) that clarified that group health plans and issuers are required to give individuals who were previously discriminated against an opportunity to enroll, including notice of an opportunity to enroll. Section 146.121(i)(3) in its entirety (and thus, the general transitional rule) was eliminated from the final regulations issued on 12/13/2006, but the special rule (set forth at 146.121(i)(4) in the interim final rules) pertaining to non-federal governmental plans

exempted under 45 CFR 146.180 was retained as 146.121(i)(2) in the final rules: “However, these regulations do not republish the expired transitional rules regarding individuals who were denied coverage based on a health factor prior to the applicability date of the 2001 interim rules. (These regulations do republish, and slightly modify, the special transitional rule for self-funded nonfederal governmental plans that had denied any individual coverage due to the plan’s election to opt out of the nondiscrimination requirements under 45 CFR 146.180, in cases where the plan sponsor subsequently chooses to bring the plan into compliance with those requirements).” (71 *Federal Register* 75014, December 13, 2006.)

In developing an estimate of the number of plans that are required to notify individuals, we assumed that all plans which have excluded individuals via an exemption election under 45 CFR 146.180 must notify all individuals who are eligible to participate in the plan. There are an estimated 4 State and 579 local governmental plans that are each required to develop a notice. We estimate that approximately 17 local governmental plans and 1 State governmental plan will develop their notices “in house.” Development of the notices is estimated to take a total of 1 hour for the State governmental plan and 17 hours for local governmental plans. The corresponding burden for work performed by service providers is anticipated to be \$200 for State governmental plans and \$40,632 for local governmental plans. These service providers would include insurance agents, brokers and third party administrators. The costs would be included in the servicing fees paid to these entities. The notices are assumed to be distributed to 19,320 participants in State governmental plans and 15,633 participants in local governmental plans. The Department estimates that the burden to distribute notices will require State governmental plans 161 hours and 15.3 hours for local governmental plans. The corresponding distribution burden performed by service providers is \$14,490 for State governmental plans and \$15,174 for local governmental plans.

Subsequent to publication of the interim final rule, only four plan sponsors notified the Centers of Medicare & Medicaid Services (CMS) in their election renewal notices (as required by 146.180(g)(2)) that they previously opted-out of the HIPAA nondiscrimination rules and are now opting-in/complying with the HIPAA nondiscrimination provisions. Due to the extremely limited number of plan sponsors that previously opted out of 146.121 but have notified CMS that they are now complying with those requirements, CMS projects that the number of notices generated as a result of 146.121(i)(2)(i) will be negligible. Be that as it may, CMS projects that in no event in subsequent years will notices generated as a result of 146.121(i)(2)(i) exceed the number estimated by CMS in 2001.

**The total burden associated with this information collection request is 194 hours.**

### **13. Capital Costs (Maintenance of Capital Costs)**

N/A. We do not expect any start up costs. ICR (b) will be built into the plans’ existing standard business practices.

### **14. Cost to Federal Government**

There is no cost to the Federal Government.

**15. Program/Burden Changes**

The purpose of this PRA package is to extend the expiration date of the previously approved requirements in OMB control number 0938-0827. None of the collection requirements have changed. This request for extension is based on the extremely limited number of plan sponsors that have notified CMS that their plans, previously exempt from the requirements of 146.121, are now in compliance.

**16. Publication and Tabulation Dates**

N/A. There are no publication or tabulation dates associated with this collection effort.

**17. Expiration Date**

This collection effort has no association with a particular form for collection which would lend itself to an expiration date. Therefore, we seek approval of a 3-year extension of the collection itself.

**18. Certification Statement**

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

**C. Collection of Information Employing Statistical Methods**

This collection does not employ statistical methods.