Supporting Statement for HIPAA Nondiscrimination Provisions: Bona Fide Wellness Programs and Supporting Regulations at 45 CFR 146.121
Agency Form Number CMS-10009

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 these 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 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-2078-P (66 FR 1421), in which we solicited comments on the information collection requirements (ICR) pertaining to bona fide wellness programs with non-Federal governmental sponsors. We received no comments. The proposed rule was finalized on 12/13/2006 and the associated information collection requirements are approved through April 30, 2009. In this Paperwork Reduction Act (PRA) submission, we request extension of the approval of those requirements which were approved by The Office of Management and Budget (OMB) under OMB control number 0938-0819.

B. Justification

1. Need and Legal Basis

The statutory and regulatory basis for this ICR is identified below along with a brief description of the requirement.

a. Bona fide wellness programs
Regulation: CMS-2078-F
Regulatory basis: 45 CFR 146.121 (f), Bona fide wellness programs
Statutory basis: Section 2702(b) of the PHS Act

Bona fide wellness programs: Section 146.121(f)(2)(v)(A) of the regulations requires the plan or issuer to disclose in all plan materials the terms of certain wellness programs including the availability of a reasonable alternative standard required under paragraph (f)(2)(iv)(A)(1) and (2) of this section. However, in plan materials that merely mention that a program is available, without describing its terms, the disclosure is not required.

2. Information Users

Plan participants and their dependents need this information to understand the rights they have under HIPAA. States and the Federal government may need the information supplied by issuers to properly perform their regulatory functions.

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, the ICR outlined in this supporting statement is the least burdensome way of ensuring compliance with this statutory and regulatory requirement.

5. Small Businesses

This ICR does not affect small businesses.

6. Less Frequent Collection

Non-Federal plans and their issuers generally revise their plan documents annually to address changes in their plan terms. The necessary plan revisions will most likely coincide with their standard business practices of updating and revising their plan documents.

7. Special Circumstances

N/A. There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice for the current submission of this information collection request was published on October 3, 2008. A 30-day Federal Register notice was also published on December 15, 2008. No comments were 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. In conjunction with the Departments of Labor and Treasury, we published an interim final rule on April 8, 1997 (62 FR 16894), soliciting further comments on the nondiscrimination provisions and, as noted above, published the proposed rule, CMS-2078-P, pertaining to bona fide wellness programs on January 8, 2001. The proposed 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 ICR.

10. Confidentiality
N/A. None of the information required to be provided under this ICR raises any confidentiality concerns.

11. Sensitive Questions
N/A. This ICR involves no 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 as follows:

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

Bona fide wellness programs: Paragraph (f)(2)(v)(A) requires the plan or issuer to disclose in all plan materials the terms of certain wellness programs including the availability of a reasonable alternative standard required under paragraph (f)(2)(iv)(A)(1) and (2) of this section. However, in plan materials that merely mention that a program is available, without describing its terms, the disclosure is not required. The disclosure of the reasonable alternative standard required under paragraph (f)(2)(iv)(A)(1) and (2) in plan materials which describe the terms of certain wellness programs is intended to provide certain individuals with sufficient and necessary information.

It is anticipated that this requirement will potentially affect the estimated 2,600 non-Federal governmental plans (respondents) that apply premium discounts or surcharges for participation in a wellness program. Each affected plan will be required to make unique changes to plan materials (responses). For purposes of calculating hourly burden, we estimate that the development of the materials is expected to take 1,300 hours for non-Federal governmental plans that make the changes "in house" (30 minutes per plan). The corresponding burden performed by service providers is estimated to be $38,000.

13. Capital Costs (Maintenance of Capital Costs)
N/A. We do not expect any start up costs. This ICR will be built into the issuers' 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 request extension of the approval of the burden associated with these requirements, approved by OMB under OMB control number 0938-0819. None of the information collection requirements have changed. There was a mathematical error in the

last PRA submission which has been corrected. 2,600 respondents * 30 minutes each = 1,300 burden hours (previously it was reported that 2,600 respondents * 30 minutes each = 100 burden hours)

16. Publication and Tabulation Dates

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

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 a three year extension from the approval date.

18. Certification Statement

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

C. Collection of Information Employing Statistical Method

This collection does not employ statistical methods.