SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995 SUBMISSIONS

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

Section 734 of the Employee Retirement Income Security Act (ERISA), which was added by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191, Aug. 21, 1996) (HIPAA), gives the Secretary of Labor, in coordination with the Secretary of Health and Human Services (HHS) and the Secretary of the Treasury, (collectively, the Departments) the authority to promulgate necessary or appropriate regulations to carry out the provisions of Part 7 of ERISA (the HIPAA provisions).

The portability provisions of Part 7 limit the extent to which group health plans and their health insurance issuers can restrict health coverage based on pre-existing conditions for individuals who previously had health coverage and make it easier for such individuals to continue their health coverage when they change jobs by limiting the ability of group health plans and health insurance issuers to exclude coverage based on a preexisting condition. The provisions limit all preexisting condition exclusion periods to twelve months (or eighteen months for certain individuals who enroll late in the plan). Further, a group health plan must reduce the twelve- or eighteen-month exclusion period by the length of an individual's previous "continuous health coverage." Continuous health coverage, in this context, means health coverage without any significant breaks in coverage. A significant break in coverage is any period without coverage that lasts for 63 days or more. Following a significant break in coverage, an individual is not entitled to any credit for prior coverage to reduce a preexisting condition exclusion period.

The Departments issued Interim Final Rules for Health Insurance Portability for Group Health Plans on April 8, 1997 (67 FR 16894), and Final Regulations for Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers under HIPAA Titles I & IV on December 30, 2004 (69 FR 78720). See 29 CFR 2590.701-1 through 701-7. These regulations impose certain information collection and other requirements mandated by portability provisions enacted in Section 701 of HIPAA.

In order to offset burdens on plans and issuers, the regulations require participants to demonstrate their prior creditable coverage in some circumstances. In order to help balance the burdens shifted to the participants, the regulations provide the following protections relating to providing prior creditable coverage and preexisting condition exclusions:

General Notice

Plans and issuers that impose preexisting condition exclusion periods must give employees eligible for coverage, as part of any enrollment application, a general notice that describes the plan's preexisting condition exclusion, including that the plan will reduce the maximum exclusion period by the length of an employee's prior creditable coverage. If there are no such enrollment materials, the notice must be provided as soon after a request for enrollment as is reasonably possible. The final regulation includes sample language for the general notice. See 29 CFR 2590.701-3(c). This language is likely to reduce the cost of providing the notice.

Plans that use the alternative method of crediting coverage provided in the regulations must disclose their use of that method at the time of enrollment and describe how it operates. They must also explain that a participant has a right to establish prior creditable coverage through a certificate or other means and to request a certificate of prior coverage from a prior plan or issuer. Finally, plans or issuers must offer to assist the participant in obtaining a certificate from prior plans or issuers, if necessary. See 29 CFR 2590.701-4(c)(4).

Individual Notice

Before a plan or issuer may impose a preexisting condition exclusion on a particular participant or dependent, it must give the individual written notice describing the length of the preexisting condition exclusion that will be imposed and the length of offsetting prior coverage the plan has recognized (individual notice). The individual notice must also describe the basis for the plan's decision regarding prior creditable coverage, an explanation of the individual's right to submit additional evidence of creditable coverage, and any appeal procedure established by the plan or issuer. The notice need not identify any medical conditions that could be subject to the exclusion.
The general notice and the individual notice both protect individuals by informing them of their Part 7 rights, enabling them to take any necessary corrective action, exercise their rights, and to understand the plan's provisions and how they plan to his or her personal situation.

2. *Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.*

The information collections covered by this ICR are mandated third party disclosures of information by group health plans and issuers to individuals eligible for group health coverage and/or participants in such plans against whom preexisting condition exclusions may be imposed. The information is necessary to enable individuals to understand and exercise their rights under Part 7 of ERISA. No information is required to be provided to the government under these regulations.

3. *Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other*

forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration for using information technology to reduce burden.

Under 29 C.F.R. § 2520.104b-1(b) of ERISA, "where certain material, including reports, statements, and documents, is required under Part I of the Act and this part to be furnished either by direct operation of law or an individual request, the plan administrator shall use measures reasonably calculated to ensure actual receipt of the material by plan participants and beneficiaries." Section 2520.104b-1(c) establishes the manner in which disclosures under Title I of ERISA made through electronic media will be deemed to satisfy the requirement of § 2520.104b-1(b), including the special enrollment notice. Under these rules, all pension and welfare plans covered under Title I of ERISA may use electronic media to satisfy disclosure and recordkeeping obligations, subject to specific safeguards.

The Department believes that a substantial number of group health plans have adopted electronic methods for providing disclosures to participants and beneficiaries in their plans that comply with the Department's regulation. However, because the notices covered by this ICR are provided soon after individuals become employees and/or covered by group health coverage, the Department has assumed that the notices will be provided in writing in connection with the initial distribution of enrollment or other group health plan information. Therefore, the burden estimates in this ICR reflect cost estimates for copying and distribution of written materials.

4. *Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.*

Before enactment of the HIPAA provisions, despite incremental state reforms in the laws affecting the group health insurance market, group health plans and health insurance issuers had not been required to notify eligible individuals of enrollment rights. This information collection therefore does not create any duplication of effort, and no similar information is already available elsewhere.

For both general and individual notices, the regulations have reduced duplication of effort required under the statutory provisions by requiring that only one notice be provided with respect to an individual, although both a group health plan and the issuer of the group health coverage under the plan are both required to provide the notices.

5. *If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.*

For the purpose of determining burden, "small entities" are defined by the Department to include employee benefit plans covering fewer than 100 participants. Although some large employers

may have small plans, most small plans are maintained by small businesses. Accordingly, assessing the impact on small plans is an appropriate substitute for evaluating the effects on small entities.

Because the Department believes that all affected individuals need the same information regarding preexisting condition exclusions regardless of whether they are covered under large or small plans, the notice requirements of the regulations apply uniformly to both large and small plans. However, the Department has provided model language for the notices, thereby reducing the burden on small plans as well as large plans.

In addition, to the extent possible, the regulations have been drafted to reflect ordinary business practices. Small plans generally reduce the costs of compliance by purchasing services from service providers experienced in satisfying disclosure requirements. Such providers are well positions to develop compliance tools and assume responsibility for providing required notices for a large number of small plans, reducing individual plan's costs by spreading development costs over multiple clients. The notice requirements are structured so that issuers can develop prototype notices that can be used without major revisions for multiple client plans.

6. *Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.*

This information collection is necessary to effectuate Congressional goals expressed in the Part 7 provisions and enable the regulated community to comply with the HIPAA portability requirements. Congress expressly intended that the certification and prior creditable coverage provisions serve as the mechanism for increasing the portability of health coverage for plan participants and their beneficiaries. Without the Departments' guidance, plans would be uncertainty about how to administer the statutory requirements and eligible individuals and plan participants would have greater difficulty in understanding and exercising their rights under Part 7. The notice requirements are limited in scope and frequency; further reducing the frequency of collection would not be possible without eliminating the usefulness of the information required to be provided.

7. *Explain any special circumstances that would cause an information collection to be conducted in a manner:*
   - *requiring respondents to report information to the agency more often than quarterly;*
   - *requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;*
   - *requiring respondents to submit more than an original and two copies of any document;*

- *requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;*
- *in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;*
- *requiring the use of a statistical data classification that has not been reviewed and approved by OMB;*
- *that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or*
- *requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.*

None.

8. *If applicable, provide a copy and identify the data and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.*

   Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

   Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The Federal Register Notice describing the Department's proposed extension of this information collection was published in the **Federal Register** on July 19, 2006, seeking public comment. No comments were received in response to this notice.

9. *Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.*

None.

10. *Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.*

No assurance of confidentiality has been provided.

11. *Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.*

None.

12. *Provide estimates of the hour burden of the collection of information. The statement should:*
    - *Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.*
    - *If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.*
    - *Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 13.*

The Department determined the number of private-sector group health plans affected by this information collection (respondents) from data in the 2004 Medical Expenditure Panel Survey Insurance Component (MEPS-IC), which indicated approximately 2.5 million such plans, of which approximately 64,000 were assumed to have 100 or more participants (large plans) and approximately 2.4 million were assumed to have fewer than 100 participants (small plans). The Department assumed, based on the most recent available statistics from the 2002 Kaiser Family Foundation Employer Health Benefits Survey, that 30 percent of all group health plans

have provisions imposing some sort of preexisting condition exclusion. Our calculations assume that this share was the same for all types and sizes of plans. The total number of plans affected by this information collection was therefore reduced to roughly 700,000.

The two separate notices included in this information collection must be provided to different populations. The first (to whom the general notice must be provided) consists of all individuals who annually start a new private-sector job and are offered health coverage under a group health plans with a preexisting condition exclusion. Using the 2003 Medical Expenditure Panel Survey Household Component (MEPS-HC), we estimated that 8.6 million individuals begin a new job each year. Assuming that 30 percent of these individuals are annually offered coverage under plans with preexisting condition exclusions, we estimate that group health plans will be required to provide 2.6 million individuals annually with a general notice of preexisting condition exclusion due to this rule.

The second population (to whom the individual notice must be provided) consists of individuals who annually begin coverage under a group health plan and upon whom the plan imposes preexisting condition exclusion because the individual has less than one year of prior creditable coverage. Using the 2003 Medical Expenditure Panel Survey Household Component (MEPS-HC), we estimated that of the 17.9 million individuals who either annually start a new job or are dependents of new job starters, 4.2 million did not have prior creditable coverage in the previous 12 months. Assuming that 30 percent of these individuals are enrolled in plans with preexisting condition exclusions, we expect that group health plans will need to provide 1.3 million individuals annually with individual notices of insufficient prior coverage.

The Department also made assumptions concerning the manner in which plans would satisfy the information collection requirements:

The Department is aware that a large proportion of group health plans employ service providers to satisfy various disclosure requirements, including these notice provisions. It was assumed, for this burden analysis, that all small group health plans (2,428,933 plans) will hire service providers for these notices and that 75 percent of large plans (48,085 plans) would also do so. The total number of plans, large and small, assumed to use service providers is therefore estimated at 2,477,018 (2,428,933 + 48,085), or approximately 2.5 million plans.[1] For purposes of this analysis, paperwork burden for the plans that hire service providers is treated entirely as cost burden and is described in the response to Item 13, below.

The remaining 16,028 large plans (out of a total of approximately 2.5 million plans) -- a very small fraction of plans, less than 1 percent -- are assumed to use in-house resources to comply with this information collection. All of these plans are large plans, and, because large plans in general are assumed to cover 73 percent of all participants in group health plans, the Department

1 These assumptions are consistent with the Department's assumptions concerning preparation of other required participant disclosures, such as summary plan descriptions (SPDs).

estimates that the 25 percent of large plans that use in-house resources will provide a disproportionate number of the total annually required notices, estimated at 18 percent of the annually required notices, or 462,687 general notices and 227,133 individual notices.

The hour burden arising from each of the two notice requirement has been determined as follows:

General notice

The Department has assumed preparation and distribution of the general notices will require an average of 0.50 minutes per notice. This estimate is sufficient to include any start-up time needed by a particular plan that is newly established in any year and is required to develop the original of the identical notice that each eligible employee will receive, especially since the regulations provide model language for this notice. Of the total of approximately 2.6 million general notices required to be provided per year, 18 percent or 462,687 notices are assumed to be distributed by large plans through use of in-house resources, while the remaining 82 percent of general notices (or 2,107,798 notices) are assumed to be distributed for plans by service providers (these figures are weighted by the number of participants in the plans distributing notices in house and through service providers.) The annual hour burden arising from distribution of the general notices is therefore estimated at a little under 3,856 hours (462,687 notices * 0.50 minutes per notice). The equivalent cost of this hour burden, at $26 per hour for clerical services, is estimated at about $100,249.[2]

Individual notice

The Department estimated that plans would require an average of 2 minutes to prepare and distribute each individual notice, since the plan's standard notice language would need to be supplemented with specific information pertinent to the individual's prior creditable coverage and resulting preexisting condition exclusion under the plan.[3] The aggregate number of new employees and their dependents each year under plans with preexisting condition exclusions to whom the individual notice must be provided was estimated at 1.3 million, of which 227,133 (18%) was estimated to be provided by large plans through use of in-house resources. The hour burden arising from distribution of these notices is therefore estimated at 7,571 hours (227,133 notices * 2 minutes per notice) which translate to $196,849 in equivalent costs.

2 Hourly wage estimates are based on the hourly wage and benefits for these types of workers in the DC Metropolitan Area as reported by the 2005 National Compensation Survey and the 2006 Employer Cost for Employee Compensation.

3 As with the general notice, the Department believes that this estimate is adequate to cover any time spent by a particular plan, in its first year of operation, to develop a prototype individual notice for that plan.

The following tables summarize the estimated hour burden, and the equivalent dollar value of the hour burden, for those plans that meet this obligation in-house rather than using service providers:

Category	In-house Notices	Burden hours	Equivalent cost
General Notice	462,687	3,856	$100,249
Individual Notice	227,133	7,571	$196,849
Total	689,820	11,427	$297,098

Because the Departments of Labor and Treasury share the paperwork burden of this information collection equally,[4] the total annual hour burden allocated to the Department of Labor is: [5]

Burden hours	Equivalent Cost
5714	$148,549

13. *Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).*
    - *The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operational and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining and disclosing or providing information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over*

4 Under the HIPAA portability provisions (see section 701 of ERISA and section 9801 of the Internal Revenue Code), the Department of Labor and the Department of the Treasury share enforcement jurisdiction against group health plans and employers. The two Departments therefore account for one-half of the paperwork burden created by the parallel regulations they each have promulgated. The Department of Health and Human Services, in comparison, has only secondary jurisdiction for these provisions against issuers acting as insurers, who are subject to the primary jurisdiction of States that implement the HIPAA requirements under State law.

5 Unrounded actual numbers have been entered into the ROCIS ICR Module, for purposes of calculating the burden, to produce the following results for the first IC (General Notices): 747,914 respondents, 2,570,485 responses, 3.44 responses per respondent, and 0.00075 burden hours per response. The same approach for the second IC (Individual Notices) produced the following results: 747,914 respondents, 1,261,852 responses, 1.69 responses per respondent, and 0.003 burden hours per response.

which the costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

- *If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing the cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60 day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.*
- *Generally, estimates should not include purchases of equipment or services, or portions thereof, made:(1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associate with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.*

The Department's assumptions regarding the estimated numbers of affected plans and notices required to be provided annually are described in the response to Item 12, above. As stated in that response, the Department has assumed that all small plans and 75 percent of large plans affected by this information collection will hire service providers to comply with its requirements. The total number of plans that will hire service providers is estimated at approximately 2.1 million plans. Those plans are further estimated to provide, annually, 82 percent of the notices (2,107,798 general notices and 1,034,719 individual notices). Cost burden for the plans hiring service providers includes fees paid by the plans for service provider time and for the direct costs to the service providers of distributing notices.

For plans using in-house resources, cost burden includes only the direct costs incurred by the plans to distribute the required notices (462,687 general notices and 227,133 individual notices).

General Notice

The Department assumed that service providers would charge client plans at the most a nominal fee for development of a prototype notice, since the development costs would be spread by the service provider across multiple plan clients. No burden is therefore assumed for development of the general notice for any respondent. The Department further assumed that a service provider would charge a plan for distribution of general notices an amount based on time spent that would approximate $71 per hour (representing a combination of lower-rate clerical time and higher-rate professional time), plus an overhead charge for materials and other expenses, and

that service providers would need 0.50 minutes per notice to complete a distribution for a plan.[6] Overhead charge for service providers and additional direct costs for in-house distribution was estimated at $.50 per notice. The following chart sets out the results of the application of these assumptions:

Category	Service provider notices	Service provider fees (hours plus overhead)	In-house notices	In-house direct cost
General Notice	2,107,798	$667,469	462,687	$46,269
Individual Notice	1,034,719	$1,414,115	227,133	$113,567
Total	3,142,517	$2,081,584	689,820	$159,835

The aggregate annual cost burden for these notice requirements is therefore $2,241,420 ($2,081,584 + $159,835). The 50 percent portion of this annual cost burden allocated to the Department of Labor is $1,120,710.[7]

14. *Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.*

None.

15. *Explain the reasons for any program changes or adjustments reporting in Items 13 or 14 of the OMB Form 83-I.*

There are no program changes to this ICR since the last submission of an 83-C Change Worksheet in 2004. The Department has updated the number of plans (respondents) based on more recent information and has revised its methods for determining number of responses,

6 Hourly wage estimates are based on the hourly wage and benefits for these workers in the DC Metropolitan Area as reported by the 2005 National Compensation Survey and the 2006 Employer Cost for Employee Compensation.
7 Unrounded actual numbers have been entered into the ROCIS ICR Module, for purposes of calculating the burden, to produce the following results for the first IC (General Notices): 747,914 respondents, 2,570,485 responses, 3.44 responses per respondent, and costs of $0.1388 per response. The same approach for calculating burden for the second IC (Individual Notices) produced the following results: 747,914 respondents, 1,261,852 responses, 1.69 responses per respondent, and costs of $0.6053 per response.

which has caused in increase in that number and a corresponding increase in the hour burden. The assumptions for costs (wage rates, postage, etc.) have also been updated, causing an increase in the annual cost burden.

16. *For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.*

The results of this collection of information will not be published.

17. *If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.*

There are no forms on which to display the expiration date. The information collection will display a currently valid OMB control number.

18. *Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB 83-I.*

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

Not applicable. The use of statistical methods is not relevant to this collection of information.