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.*

The Patient Protection and Affordable Care Act (the Affordable Care Act) was enacted by President Obama on March 23, 2010. Section 2719A of the PHS Act, as added by the Affordable Care Act, and the Department's interim final regulation (29 CFR 2590.715-2719A) that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee.

The statute and the interim final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer.

The statute and these interim final regulations also provide that a group health plan, or a health insurance issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology.

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, paragraph (a)(4) of the interim final regulations requires such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. Model language is provided in these interim final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

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 Patient Protection Notice used by health plan sponsors and issuers to notify certain individuals of their right to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization.

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.*

The regulation does not restrict plans or issuers from using electronic technology to provide either disclosure. The Department of Labor's regulations under 29 C.F.R. § 2520.104b-1(b) provide that, "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 29 CFR 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). Section 2520-107-1 establishes standards concerning the use of electronic media for maintenance and retention of records. 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 Government Paperwork Elimination Act (GPEA) requires agencies to allow customers the option to submit information or transact with the government electronically, when practicable. Where feasible, and subject to resource availability and resolution of legal issues, EBSA has implemented the electronic acceptance of information submitted by customers to the federal government.

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.*

The Affordable Care Act amended the Employee Retirement Income Security Act, the Internal Revenue Code, and the PHS Act. Accordingly, both the Department of Health and Human Services (HHS) and the Department of the Treasury (Treasury) will require plans and issuers to provide the Patient Protection Notice. There will be no duplication of effort with HHS and Treasury, however, because only the Department of Labor oversees ERISA-covered group health plans.

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.*

The information collection does not impact small businesses or entities.

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.*

If this information were conducted less frequently, affected individuals would not be informed of their right to **(1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization.**

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 date 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 interim final regulation provides the public with a 60-day period to submit written comments on the rule.

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.*

Not applicable

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.*

Not applicable.

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 14.*

- *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 14.*

PHS Act 2719A and the interim final regulations affect only plans and participants that use health care requirements that require participants to designate a primary care physician and are in non-grandfathered plans. The Departments assume that this is most likely to happen in HMO- and Point-of-Service (POS) type arrangements. Therefore, the Department has estimated

the number of plans and participants that have HMO- or POS- type coverage that are not grandfathered group health plans.

The Department estimates that there are 2.7 million small and 72,000 large ERISA-covered plans. Data obtained from the 2009 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 19 percent of small plans and 33 percent of large plans have an HMO option and that 37 percent of small plans and 16 percent of large plans offer a POS option. While not all HMO and POS options require the designation of a primary care physician or a prior authorization or referral before a woman can visit an OB/GYN, the Department is unable to estimate this number. Therefore, these estimates should be considered an overestimate of the number of affected entities.

In addition, the Department has estimated that 22 percent of plans will relinquish their grandfathered status and be subject to these interim final regulations in 2011, because the Patient Protection Notice requirement only applies to non-grandfathered plans. This leads to an estimated 338,000 plans (respondents) in the first year that will be subject to these interim final regulations in 2011. A similar calculation was done for 2012 and 2013, and the three-year average number of respondents is 261,860.

(2.7 million*(0.19+0.37) + 72,000*(0.33+0.16))*0.22 = 340,401[1])

The Departments also estimated that approximately 8,006,000 participants in HMO and POS options are respondents that will receive the notices. Using data from the March 2008 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey, the Department calculated that there were nearly 16.9 million policy holders in HMO options, and 50.3 million policy holders in a POS or a PPO. The Departments used data from the Kaiser/RHET survey to separate the combined POS/PPO category. The survey found that 19 percent of covered workers at small employers were in POSs and 49 percent were in PPOs and that 6 percent of covered workers at large employers were in POSs and 65 percent were in PPOs. The ratio of covered workers in POSs to covered workers in PPOs was then calculated and used to estimate the portion of the 50.3 million policy holders in the POS/PPO category that were in POS arrangements. This was then multiplied by 22 percent to approximate the number of policy holders in non-grandfathered plans. A similar calculation was done for 2012 and 2013, and the three-year average number of responses is 6,186,404.

(16.9 million+50.3 million*(0.19/0.49))*0.22 = 8,008,898[2])

In order to satisfy the interim final regulations' patient protection disclosure requirement, the Departments estimate that those most likely to be affected will by the approximately 339,000 ERISA-covered plans that receive coverage from an HMO or POS. These plans will need to notify an estimated 8.0 million policy holders of their plans' policy in regards to designating a primary care physician and for obstetrical or gynecological visits. The following estimates are based on the assumption that 22 percent of group health plans will not have grandfathered health

1 This number is rounded.
2 This number is rounded.

plan status in 2011. Because the interim final regulations provide model language for this purpose, the Departments estimate that five minutes of clerical time (with a labor rate of $26.14/hour) will be required to incorporate the required language into the plan document and ten minutes of an human resource professional's time (with a labor rate of $89.12/hour) will be required to review the modified language. Therefore, the Departments estimate that plans will incur a one-time hour burden of 85,000 hours with an equivalent cost of $5.8 million to meet the disclosure requirement in the first year.

Plans that relinquish their grandfathered status in subsequent years also will become subject to this notice requirement and incur a cost to prepare and distribute the notice in the year they relinquish their grandfathered status. The Departments estimate a total hour burden of 62,000 hours in 2012 and 50,000 in 2013 for plans relinquishing their grandfathered status in 2012 or 2013. The Department of Labor equally shares this burden with the Department of Treasury. Therefore, the three-year average burden for the Department of Labor is of approximately 33,000 hours with an equivalent cost of approximately $2.2 million.

13. *Provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12.)*

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the interim final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Departments estimate that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically. This results in a cost burden of $124,000 ($0.05 per page*1/2 pages per notice * 8.0 million notices*0.62). There also will be an estimated total cost burden of $90,000 in 2012 and $73,000 in 2013 for plans relinquishing their grandfathered status in 2012 or 2013. The Department of Labor shares this cost burden with the Department of Treasury. Therefore, the three-year average cost burden for the Department of Labor is $48,000.

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.*

Not applicable.

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

This is a new information collection.

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.*

There are no plans to publish the results of this collection of information.

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.*

The OMB expiration date will be published in the Federal Register following OMB approval.

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

None.

B. Collections of Information Employing Statistical Methods

Not applicable.