SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSIONS

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, Public Law 111-148, (the Affordable Care Act) was enacted by President Obama on March 23, 2010. As part of the Act, Congress added PHS Act section 2719, which provides rules relating to internal claims and appeals and external review processes. On July 23, 2010 interim final regulations (IFR) implementing section 2719 of the PHS Act were published. These interim final regulations were amended in June 2011. The amended IFR specified rules governing the internal claims and appeals and external review processes.

With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503-1 (the Department of Labor (DOL) claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations. Paragraph (b)(3)(i) requires issuers offering coverage in the individual health insurance market to also comply with the DOL claims procedure regulation as updated by the Secretary of Health and Human Services (HHS) in paragraph (b)(3)(ii) of the IFR for their internal claims and appeals processes.

The DOL claims procedure regulation requires plans to provide every claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The claims regulation also requires that any adverse benefit determination upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. Paragraph (b)(3)(ii)(C) of the IFR adds an additional requirement that non-grandfathered ERISA-covered group health plans provide to the claimant, free of charge, any new or additional evidence considered relied upon, or generated by the plan or issuer in connection with the claim.[1] As discussed in more detail in items 12 and 13 below, this requirement increases the administrative burden on plans and issuers to prepare and deliver the additional information to the claimant.

1 Such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date. Additionally, before the plan or issuer can issue an adverse benefit determination on review based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale. The rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.

Also PHS Act section 2719 and the IFR provides that health insurance issuers and self-funded non-federal governmental health plans must comply either with a State external review process or a Federal review process. The IFR provides a basis for determining when health insurance issuers and self-funded non-federal governmental health plans must comply with an applicable State external review process and when they must comply with the Federal external review process. The hour and cost burden associated with implementing an external review program also is discussed in more detail in items 12 and 13, below. PRA coverage and any burdens contained herein recognize requirements that we have identified in the NAIC Uniform Health Carrier External Review Model Act that must be met or exceeded.

The claims procedure regulation imposes information collection requirements as part of the reasonable procedures that an employee benefit plan must establish regarding the handling of a benefit claim. These requirements include third-party notice and disclosure requirements that the plan must satisfy by providing information to participants and beneficiaries of the plan.

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 collection requirements included in the claims procedure regulation ensure that participants and beneficiaries (claimants) receive adequate information regarding the plan's claims procedures and the plan's handling of specific benefit claims. Participants and beneficiaries need to understand plan procedures and plan decisions in order to appropriately request benefits and/or appeal benefit denials.

The information collection requirements are necessary for the Federal external review process to provide an independent external review as requested by claimants.

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 claims regulation and the IFR do not restrict plans' use of electronic technology to process and pay claims, to maintain information as to the basis for claim determination, and to generate correspondence related to claims processing decisions. This burden estimate incorporates the Department's assumptions, described in the response to item 12, below, concerning the rate of use by plans and issuers of electronic means of communication.

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.*

No duplication with other Federal statutes exists. In some circumstances, states may require substantially similar information to be provided to insured persons. However, no duplication occurs because the same information disclosure may be used to satisfy duplicative or overlapping requirements.

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 regulation applies to all employee benefit plans and therefore is likely to affect small entities that provide benefits. For the purposes of the IFR, small entities that fall under HHS' regulatory authority would include small insurers in states subject to the Federal External Review process and small self-insured nonfederal governmental health plans.

For small insurers, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), HHS used a data set created from the 2009 National Association of Insurance Commissioners (NAIC) Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, HHS used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. HHS estimated that approximately 6.3 percent of insurers qualified as small entities with less than $7 million in A&H earned premiums offering individual or group comprehensive major medical coverage. Seven million dollars in annual receipts is the size threshold for health insurers according to the Small Business Administration (North American Industry Classification System Code 524114). This estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies' other lines of business. Using data from the 2009 Current Population Survey, HHS estimates that the IFR will affect an estimated 5.73 percent of nonfederal governmental health plans that qualify as small plans.

The Department took into account the potential burden on small entities in structuring the regulation by permitting plan sponsors the maximum possible flexibility in designing their plans, including the possibility of hiring third-party service providers to carry out these administration responsibilities in order to make use of the lowest cost method of compliance available. A large majority of small plans purchase claims administration services from insurers, HMOs, and other service providers, and the Department has taken this fact into account in deriving its burden estimates. These service providers typically develop a single claims processing system to service a large number of customers, including small entities. Thus, the cost of revising and implementing the procedures is spread thinly over a large number of small plans. Moreover, small plans and their respective enrollees benefit equally from the service provider's expertise and ability to provide improved accuracy and timeliness in claims and appeals determinations.

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.*

The information collection requirements arise in connection with the occurrence of individual claims for benefits and consist of third-party notices and disclosures. No information

is reported to the Federal government other than that which is necessary for OPM to facilitate an external review. The information collection provisions of the regulation ensure that sufficient information is provided to claimants so that they may fully exercise their rights under their coverage. Without this information collection, people in the fully insured market in States with no external appeal laws would not receive their right to external review as required by PHS Act Section 2719. With the modification to the PRA package, the information collection is necessary to ensure that consumers in fully insured plans in states whose external review processes do not meet the requirements of 2719(b)(1) and 2719(b)(2) as well as the non-grandfathered self-funded non-federal governmental health plans across the country can access their rights as described in PHS Act Section 2719.

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.*

The DOL claims procedure regulation, IFR and Federal external review processes impose special timing requirements for the handling of claims in the fully insured market. Depending on circumstances indicating the urgency of the need for a claims decision, issuers may be required to notify claimants about health benefit claim determinations in fewer than 30 days.

First, for claims involving "urgent care," the regulation requires, in general, that claimants be notified of health benefit determinations "as soon as possible, but not later than 72 hours after receipt of the claim by the plan. . . ." 29 CFR 2560.503-1(f)(2)(ii). In cases involving

urgent care where the health claim is a request to extend the time period or number of treatments of ongoing medical care, this period is 24 hours. 29 CFR 2560.503-1(f)(2)(ii)(B).

Second, for "pre-service" claims, the regulation requires that claimants be notified of health benefit determinations "within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt of the claim by the plan." 29 CFR 2560.503-1(f)(2)(iii)(A). Pre-service claims involve plan requirements that a claimant obtain approval from the plan prior to receiving health care services or products in order to maintain eligibility for benefits.

Third, for "post-service" health benefit claims, the regulation requires notification of an adverse benefit determination "within a reasonable period of time, but not later than 30 days after receipt of the claim." Even though 30 days is the maximum response time for these claims, a plan must provide a determination sooner if it is reasonable to do so. Disability benefit claims are subject to a similar construct, except that the maximum response time is 45 days.

Appeals of denied claims must be decided within similar, short time limits. In addition, to facilitate external review for claimants in non-grandfathered self-funded non-federal governmental health plans and the fully insured group and individual markets subject to the Federal external review process, issuers will be required to electronically notify HHS as to whether the PHS Act 2719 applies to them, and specifies the insurance packages to which it applies. If PHS Act Section 2719 is applicable, the issuers are required to notify HHS which Federal process they are using and provide contact information for designated personnel in their appeals department, including names, mailing address, telephone numbers, facsimile numbers and electronic mail addresses. Issuers will also be required to provide the claimants' relevant file to OPM in fewer than five days upon request from OPM.

These timing requirements are related to important policy objectives in an area of important public concern. For example, the shortest time frame for "urgent care" claims applies only under circumstances in which delay could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or where delay would subject the claimant to severe pain. The next shortest time frame applies under circumstances in which medical care, while not urgent, has not been provided to a claimant who needs treatment for a medical problem and where the plan itself requires pre-approval of the medical care before providing coverage. Post-service health claims and disability claims also involve important concerns relating to the sick and disabled, but under these circumstances plans may take at least 30 days to respond if it is reasonably necessary to do so.

Another reason why these time frames are important is that these notices relate to the payment of money by a plan to claimants to whom fiduciary responsibilities are owed. Without enforcement of reasonable deadlines, payers could be given a financial incentive to delay the payments, and this would likely be inconsistent with appropriate fiduciary standards.

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 rule that displayed on June 22, 2011, served as the emergency Federal Register notice. We have requested emergency OMB review and approval of the information collection requirements by July 1, 2011.

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

Not applicable.

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

This information collection request (ICR) involves disclosures of information by issuers to enrollees. Issues of confidentiality between third parties do not fall within the scope of this information collection request.

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 14.*

The Department estimates that this information collection affects 28,000 respondents in its first year. The number of respondents will increase over time as more plans lose grandfathered status and must comply with the regulations. The frequency of response will be on occasion, mirroring the frequency of benefit claims that require responses, totaling about 70 million per year. The hour burden, which will also increase over time as additional plans lose grandfathered status and as federal external review process requirements change (see below), is estimated to be 570,800 hours the first year.

Under PHS Act section 2719 and the interim final regulations, all sponsors of non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must comply with all requirements of the Department of Labor's DOL claims procedures regulation as well as the new standards that are established by the Secretary of Labor and the Secretary of Health and Human Services in paragraphs (b)(2) and (b)(3) of the interim final regulations. These estimates include only ongoing costs of compliance with the statute and the interim final regulations.

Ongoing burdens are a function of claims volume, as well as the denial and appeal rates of plans.

TABLE. 1--*Estimated Claims and Appeals in Non-grandfathered Coverage (in thousands)*

	2011		2012		2013	
	Government Sector ESI	Individual Market	Government Sector ESI	Individual Market	Government Sector ESI	Individual Market
Total Enrollees	39,000	15,084	39,000	15,084	39,000	15,084
Non-Grandfathered Enrollees	6,898	6,034	12,576	9,654	17,250	11,826
Total Claims	70,360	61,543	128,275	98,469	175,947	120,625
Pre-Service						
Claim Approved	1,794	1,569	3,271	2,511	4,487	3,076
Claim Denied	317	277	577	443	792	543
Post-Service						
Claims Approved	55,473.0	45,190.5	101,134.3	72,304.8	138,719.3	88,573.4
Claim Denied	10,237	8,955	18,664	14,327	25,600	17,551
Claim Extended	2,539	5,552	4,629	8,883	6,349	10,882

Total Internal Appeals	24.1	52.8	44.0	84.5	60.4	103.5
Appeals Upheld	9.7	21.1	17.6	33.8	24.1	41.4
Appeals Denied	14.5	31.7	26.4	50.7	36.2	62.1
Medical subtotal	7.0	15.3	12.7	24.4	17.4	29.9
Appeals Upheld	2.8	6.1	5.1	9.8	7.0	12.0
Appeals Denied	4.2	9.2	7.6	14.6	10.5	17.9
Administrative subtotal	17.2	37.5	31.3	60.1	42.9	73.6
Appeals Upheld	6.9	15.0	12.5	24.0	17.2	29.4
Appeals Denied	10.3	22.5	18.8	36.0	25.8	44.1
Total New External Appeals	0.6	0.2	1.1	0.3	1.5	0.4

The transaction burden will vary widely with the type and complexity of claim in question, but the mix of claims and associated burdens generally are expected to be similar across plans of the same type. The average time required for the information collection associated with any particular type of health benefit claim transaction will range from one minute for certain routine automatic notices to four and a half hours for certain disclosures on request following adverse claim determinations.

The Department estimates that approximately 93 percent of large group health and all small group health plans administer claims using a third-party provider. Approximately 5 percent of individuals covered by group health insurance as well as all people covered in the individual market insurance claims are administered in-house. In-house administration burdens are accounted for as hours, while purchased services are accounted for as dollar costs. The hourly burden as well as mailing costs for plans processing claims in-house is described below:

TABLE 2.--*In-House Burden Hours (in thousands)*

	2011		2012		2013	
	Hours	Mailing Cost	Hours	Mailing Cost	Hours	Mailing Cost
Pre-Service						
Claim Approved	27.6	$160.7	44.4	$259.0	54.8	$319.5
Claim Denied	9.7	$28.4	15.7	$45.7	19.3	$56.4
Post-Service						
Claim Denied	314.5	$917.1	506.8	$1,477.9	625.1	$1,822.9
Claim Extended	94.5	$551.2	151.7	$884.6	186.3	$1,086.7
Denial Appeal						
Total	116.7	$29.1	264.7	$46.7	325.2	$57.4
Appeal Approved	28.6	$11.6	60.8	$18.7	74.7	$23.0
Appeal Denied	88.1	$17.5	203.9	$28.0	250.5	$34.4

Medical	70.1	$8.4	190.1	$13.5	233.5	$16.6
Claim Approved	28.1	$3.4	60.0	$5.4	73.7	$6.6
Claim Denied	42.1	$5.0	130.1	$8.1	159.8	$10.0
Administrative	46.5	$20.7	74.7	$33.2	91.7	$40.8
Claim Approved	0.5	$8.3	0.8	$13.3	1.0	$16.3
Claim Denied	46.0	$12.4	73.8	$19.9	90.7	$24.5
Fair and Full Review	3.1	$16.1	5.0	$25.9	0.2	$0.8
External Review	4.5	0.1	8.6	0.2	11.5	0.2
Total	**570.8**	**$1,702.9**	**997.2**	**$2,740.0**	**1222.8**	**$3,343.9**

Note: Assumed that 7 percent of large plan process these claims in-house in the Group Market. Large plans account for 67.8 percent of policy-holders and therefore 4.7 percent of claims are processed in-house. Assumed all Individual Market claims are processed in-house.

Total burden hours are estimated at 570,800 hours in 2011, 997,200 hours in 2012 and 1,222,800 hours in 2013. Equivalent costs are estimated at $28.2 million in 2011, $57.4 million in 2012 and $70.4 million in 2013. This hour burden and estimated costs burden takes into account the burden that is associated with the external review process and described below.

External Review Process

This ICR is being amended to account for the added burden of the disclosure requirements of the Federal external review process for health insurance issuers in States where State external review processes do not meet the (b)(1) or (b)(2) standard of PHS Act 2719 ("health insurance issuers") See ["Guidance on External Review for Group Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage and Guidance for States on State External Review Processes" on CCIIO website – http://cciio.cms.gov] and self-funded non-federal governmental plans not subject to a compliant state or territory external review process [See "Instructions for Self Insured Non-Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage on How to Elect a Federal External Review Process " on CCIIO website – http://cciio.cms.gov]. Note that both health insurance issuers and self-funded non-federal governmental plans have an option of contracting with Independent Review Organizations (IROs) as described in the Department of Labor Technical Release 2010-01.

It is assumed that self-funded non-federal governmental plans will use the HHS Federal external review process because this will result in less administrative burden since they do not need to initiate contracts on their own. Additionally, non-federal governmental plans will not have to pay for independent reviews under the HHS process. It is further assumed that 50 percent of external appeals in the fully insured market in states that do not meet the standards outlined above will be determined by the HHS Federal external review process. It is estimated to be 50 percent because of the unknown interplay of several factors that will influence issuers' choice of which Federal external review process to use. These factors are:

1. Health insurance issuers in the HHS Federal external review process would have a lower administrative and cost burden when compared with those in the

Department of Labor process. Issuers that choose the HHS process would not have to enter into a private contract with IROs where the issuers would be forced to pay for their own external reviews.

2. Many health insurance issuers act as third party administrators for self-insured ERISA plans and accordingly, already contract with IROs. Therefore, they may be incentivized to utilize the process described in the Department of Labor Technical Release 2010-01 in order to achieve continuity across their external review process.
3. Finally, some issuers may be apprehensive about direct Federal involvement in their process and prefer to contract privately with IROs as prescribed by the Department of Labor Technical Release 2010-01.

Both health insurance issuers and self-funded non-federal governmental health plans must disclose electronically to HHS whether they will use the HHS administered Federal external review process or are following the Department of Labor Technical Release 2010-01. This burden is accounted for in this ICR.

First, health insurance issuers and self-funded non-federal governmental plans that have opted to use the either HHS Federal external review process or the Department of Labor's Federal external review process ("applicable plans and issuers") will be required to notify HHS as to which Federal external review process they will be using. If they are using the HHS process, they will also be required to submit to HHS all notices pertaining to external review rights including the notice of adverse benefit determination and the notice of final internal adverse benefit determination. If these notices are updated at any time, updated copies of these notices will need to be submitted to HHS.

The HHS Federal external review process also requires[2] 1) The OPM appointed examiner ("the examiner") to conduct a preliminary review of a claimant's eligibility for external review 2) Applicable plans and issuers to provide the examiner with documentation and other information considered in making adverse benefit determinations or final adverse benefit determinations 3) The examiner to notify the claimants who are ineligible for external review that they are ineligible 5) The examiner to forward to the applicable plan or issuer any information submitted by the claimant; 6) That if the applicable plan or issuer reverses its decision, it must notify the claimant and the examiner; 7) The examiner to notify claimant and the applicable plan or issuer of result of final external review(burden previously accounted for); 8) The examiner to maintain records for six years.

Health insurance issuers and self-funded non-federal governmental plans in States where State external review processes do not meet the (b)(1) or (b)(2) standard of PHS Act 2719 that decide to follow the Department of Labor's Federal external review process will be subject to the following different set of requirements. 1) Issuers must conduct a preliminary review of claimant requests for external review in order to determine eligibility. 2) Following the preliminary review; issuers must notify the claimant whether or not they are eligible for external review 3) if the claimant is eligible, the issuer must forward to the IRO all documentation and

2 Note that these federal external requirements are not new and have been previously accounted for. The change in this modification is that the process applies to all fully insured plans in states whose external review processes do not meet the requirements in 2719(b)(1) and 2719(b)(2) as well as to all non-grandfathered self-funded non-federal governmental health plans that choose to use the HHS process. This choice is new as well.

other information considered when making its adverse benefit determination. 4) The IRO must forward all information submitted by the claimant back to the issuer. 5) Next, the IRO must notify claimant and the applicable plan or issuer of result of final external review. 6) Finally, the IRO must retain its records for six years.

It is estimated that there will be 7,440 external reviews conducted in a year for the affected population.[3]

The total hour burden associated with the Federal external review process for affected self-funded non-federal governmental health plans and health insurance issuers is 4522 with an equivalent cost of $123,907. This number includes 4,496 hours accounting for the disclosure requirement at an equivalent cost of $123,236 and 26 hours to conduct preliminary reviews of external review requests coming with an equivalent cost of $671. We made reasonable estimates for the amount of time it would take for each of the steps outlined above, assuming that a clerical worker could prepare most of the documents that would need to be sent forward. We used salary data provided by the Department of Labor National Occupational Employment Survey.

All of these hours are attributed to the HHS Federal Process in addition to the overall disclosure requirements because we are assuming that all of the self-funded non-federal governmental plans will choose the HHS process. Furthermore, the burden for health insurance issuers and self-funded non-federal governmental health plans that are not yet in the HHS process is not accounted for in 2011 because they have until January 1, 2012 to comply.

Overtime, as more plans lose grandfathered status, the number of health insurance issuers and self-funded non-federal governmental health plans subject to the Federal external review process will increase; the hour burden will increase proportionately, resulting in an estimated hour burden of 8,559 hours in 2012 which includes 603 burden hours for preliminary review and 7,956 burden hours for disclosure. There is an estimated $233,792 equivalent cost associated with 2012 which is comprised of $15,768 for preliminary review and $218,024 for disclosure.

The hour burden and equivalent cost for the HHS process in 2013 is estimated to be 11,465 hours and $313,178 respectively. The total disclosure hour burden associated with 2013 is estimated to be 10,657 hours with an equivalent cost of $292,056; the total preliminary review hour burden is estimated to be 808 hours with an equivalent cost of $21,122.

There is no record retention burden placed on self-funded nonfederal governmental plans and health insurance issuers that elect the HHS process because OPM's contractor retains all records.

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 or 14).*

As indicated in question 12, the bulk of group market claims will be processed by third-party service providers. Total costs are estimated by multiplying the number of responses by the amount of time required to prepare the documents and then multiplying this by the appropriate hourly cost of either clerical workers ($26.14), doctors ($154.07) or lawyers (119.03),[4] and then

3 Rate of external reviews is .03% and based on the experience of OPM that will be administering the HHS external review process.

4 EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational

adding the cost of copying and mailing responses (0.54 each for those not sent electronically). These costs are described below:

Table 3.--*Out-House Burden Cost (in thousands)*

	2011			2012			2013		
	Hours Cost	Mailing Cost	Total Costs	Hours Cost	Mailing Cost	Total Costs	Hours Cost	Mailing Cost	Total Costs
Pre-Service									
Claim Approved	$744.9	$166.2	$911.1	$1,358.1	$303.0	$1,661.1	$1,862.8	$415.6	$2,278.4
Claim Denied	$262.9	$29.3	$292.2	$479.3	$53.5	$532.8	$657.5	$73.3	$730.8
Post-Service									
Claim Denied	$8,500.9	$948.3	$9,449.2	$15,498.3	$1,728.9	$17,227.1	$21,258.0	$2,371.4	$23,629.4
Claim Extended	$1,054.1	$235.2	$1,289.3	$1,921.8	$428.8	$2,350.5	$2,636.0	$588.1	$3,224.1
Denial Appeal									
Total	$6,972.8	$12.4	$6,985.2	$12,712.2	$22.7	$12,734.9	$17,436.6	$31.1	$17,467.6
Appeal Approved	$1,870.0	$5.0	$1,875.0	$3,409.3	$9.1	$3,418.4	$4,676.3	$12.4	$4,688.7
Appeal Denied	$5,102.7	$7.5	$5,110.2	$9,302.9	$13.6	$9,316.5	$12,760.3	$18.6	$12,778.9
Medical	$4,610.2	--	$4,610.2	$8,404.9	--	$8,404.9	$11,528.4	--	$11,528.4
Claim Approved	$1,844.1	--	$1,844.1	$3,362.0	--	$3,362.0	$4,611.4	--	$4,611.4
Claim Denied	$2,766.1	--	$2,766.1	$5,042.9	--	$5,042.9	$6,917.1	--	$6,917.1
Administrative	$2,362.6	--	$2,362.6	$4,307.3	--	$4,307.3	$5,908.1	--	$5,908.1
Claim Approved	$26.0	--	$26.0	$47.3	--	$47.3	$64.9	--	$64.9
Claim Denied	$2,336.7	--	$2,336.7	$4,260.0	--	$4,260.0	$5,843.2	--	$5,843.2
Fair and Full Review	$36.0	$6.9	$42.9	$65.7	$12.6	$78.3	$318.8	$60.9	$379.7
External Review	--	--	$.4	--	--	$10.4	--	--	$14.0
Translation Cost	--	--	--	--	--	$430.0	--	--	$430.0
Total Costs			**$20,733.2**			**$37,874.1**			**$51,647.8**

Amendments to the Interim Final Rule Regarding Internal Claims and Appeals (June 2011)

These amendments make two changes to the interim final rules that impact the paperwork burden. The first is an amendment no longer requiring that diagnosis and treatment codes be included on notices of adverse benefit determination and final internal adverse benefit determination. Instead, these notices must include a statement notifying claimants of the opportunity to receive the codes on request and plans and issuers must then provide the codes upon request. The Departments expect that this change will lower costs, because plans and issuers will no longer have to provide the codes on the notices. Plans and issuers will incur a

Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

cost to establish procedures for receive, process, and mail the codes upon request; however, the Departments are unable to estimate such cost due to a lack of a basis for an estimate of the number of requests that will be made for the codes.

The amendments also change the method for determining who is eligible to receive a notice in a culturally and linguistically appropriate manner in the group market, and the information that must be provided to such persons. The previous group market rule was based on the number of employees at a firm. The new group market rule is based on whether a participant or beneficiary resides in a county where ten percent or more of the population residing in the county is literate only in the same non-English language.

Participants and beneficiaries residing in an affected county and speaking an applicable non-English language will now receive a one-sentence statement in all notices written in the applicable non-English language about the availability of language services. In addition to including the statement, plan and issuers are required to provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon requests.

The Department understands that oral translation services are already provided for nearly all covered participants and beneficiaries. Therefore, no additional burden is associated with this requirement of the amendment.

The Department expects that the largest cost associated with the amended rules for culturally and linguistically appropriate notices will be for plans and issuers to provide notices in the applicable non-English language upon request. Based on the American Community Survey (ACS), [5] the Departments estimate that there are about 12 million individuals living in covered counties that are literate in a non-English Language. The ACS does not have insurance coverage information. Therefore, to estimate the percentage of the 12 million affected individuals that were insured, the Departments used the percent of the population in the State that reported being insured by public employer insurance in individual coverage from the 2009 CPS.[6] This results in an estimate of approximately 1.8 million individuals who are eligible to request translation services.

In discussions with the regulated community, the Departments found that experience in California, which has a State law requirement for providing translation services, indicates that requests for translations of written documents averages 0.098 requests per 1,000 members. While the California law is not identical to the amendment to the July 2010 regulations, and the demographics for California do not match other counties, for purposes of this analysis, the Departments used this percentage to estimate of the number of translation service requests that plan and issuers can expect to receive. Industry experts also told the Departments that while the cost of translation services varies, $500 per document is a reasonable approximation of translation cost.

Using the ACS and the CPS, the Departments estimate 8.8 million insured though public employer insurance or individual coverage lives in the affected counties. Based on the

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5 Data are from the 2005-2009 American Community Survey available at www.census.gov/acs . Individuals counted reside in counties where at least 10 percent of the county speak a particular non-English language and speak English less than "very well" are counted.

6 Please note that using state estimates of insurance coverage could lead to an over estimate if those reporting in the ACS survey that they speak English less than "very well" are less likely to be insured than the state average.

foregoing, the Departments estimate that the cost burden to provide translation services will be approximately $430,000 annually (8,777,000 lives * 0.098/1000 * $500) starting in 2012.

Federal External Review Process

The changes being made to the Federal External Review Process are explained above in #12.

It is estimated that there will be a cost burden of $444 in 2011. This cost burden is a result of sending the files for the health insurance issuers and self-funded non-federal governmental health plans using the HHS process to the independent examiner at $1.44 per appeal. (Because we are assuming that all self-funded non-federal governmental plans will use the HHS process and issuers in most states other than those with no laws are not required to use the Federal external review process until January 1, 2012, this number is low). As the number of non-grandfathered plans increases and the Federal external review process requirements increase, the cost burden will increase proportionately with an estimated cost burden of $10,423 in 2012 and $13,963 in 2013.

Due to the amendments, the Department has adjusted the total estimated costs of this information collection. The Department estimates that issuers and state and local governmental plans will incur a total estimated cost burden for those plans that use service providers, including the cost of mailing all responses, of $20.7 million in 2011, $37.9 million in 2012, and $51.6 million in 2013.

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.*

The Federal external review process includes some cost burden to the government of $3,782 in FY 2011. This burden stems from the following: 1) Mailing notices to claimants that are determined ineligible for external review with the assumptions of approximately 20% of external reviews ineligible for external review.[7] 2) Mailing any documents submitted by the claimant back to the plan with the assumption that approximately 80% of eligible appeals will submit additional information.

As the number of grandfathered plans increase and federal external review requirements increase, the cost to the government is estimated to increase to $6,220 in 2012 and to $14,847 in 2013

7 This percentage of request that are ineligible is drawn from data provided by OPM on the FEHBP.

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

The amended IFR made the following policy changes that altered the predicted cost and hour burden estimates associated with this information collection request:

1. Granted health insurance issuers in States where State external review processes do not meet the (b)(1) or (b)(2) standard of PHS Act 2719 the choice of whether to follow the HHS external review process or the process outlined in the Department of Labor Technical Release 2010-01. Previously the HHS federal external review process was only available to issuers in the 3 states and 4 territories without external review laws.
2. Granted self-funded non-federal governmental health plans the choice of whether to follow the HHS external review process or the process outlined in the Department of Labor Technical Release 2010-01. Previously this choice was only available to the self-funded non-federal governmental health plans in the states and territories with no external review laws.
3. Because of the choice now available as explained in #1 and #2 above, HHS is requiring health insurance issuers and self-funded non-federal governmental health plans subject to the federal external review process to inform HHS as to which federal external review process it is choosing.
4. Changed the thresholds that determine CLAS notification requirements for group health plans.
5. Removed the requirement that diagnostic and treatment codes be recorded on the notice of adverse benefit determination. Instead, this information must be provided to claimants upon request.
6. Extended the maximum timeline allotted for the review of urgent care claims from 24 to 72 hours.

In aggregate, the total cost and hour burden estimates went from $18,995,900 and 566,200 hours in 2011 to $20,733,200 and 570,800 hours, $34,632,000 and 988,500 hours in 2012 to $37,874,100 and 997,2 hours, and $47,749,000 and 1,211,100 hours in 2013 to $51,647,800 and 1,222,800 hours because of these policy changes.

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.*

Not applicable.

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 collection of information 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.*

Not applicable; no exceptions to the certification statement.