Supporting Statement Part A
for Paperwork Reduction Act Submission
CMS-10338/0938-1099

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 an interim final rule (IFR) implementing section 2719 of the PHS Act were published. The interim final rule was amended in June 2011. The amended IFR specified rules governing the internal claims and appeals and external review processes. The Departments of Health and Human Services, Labor and Treasury are currently finalizing the IFR. The final appeals rule will be hereinafter referred to as the Appeals regulation.

With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the Appeals 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 Appeals regulation 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 the 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 made 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 Appeals regulation 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]

[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

PHS Act section 2719 and the Appeals regulation also provide that health insurance issuers and self-funded nonfederal 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 the Department 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 collected regarding the Federal external review process is used 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 Appeals regulation 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.*

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date.

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 health insurance insurers 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 dataset 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 Appeals regulation 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. The cost of revising and implementing the procedures is therefore spread widely over a large number of small plans, minimizing burden on those 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 HHS 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 noncompliant external review laws would not receive their right to external review as required by PHS Act Section 2719. 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 nonfederal 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, Appeals regulation and Federal external review processes impose special timing requirements for the handling of claims in the fully insured market and for self-funded nonfederal governmental plans. 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 time limits. In addition, to facilitate external review for claimants in non-grandfathered self-funded nonfederal 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 specify 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 and self-funded nonfederal governmental health plans that elect the HHS-administered process will also be required to provide the claimants' relevant file to the HHS external review contractor in fewer than five days upon request.

These timing requirements are related to 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 pre-service 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.

A Federal Register notice was published on November 18, 2015 (80 FR 72231), providing the public with a 60-day period to submit written comments on the ICRs. No comments were received. A 30-day Federal Register notice will publish on May 27, 2016 providing the public to submit written comments on these information collection requirements.

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.*

These ICRs involve no sensitive questions.

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 95,500 respondents in the first year. The number of respondents will continue to increase over time as more plans relinquish grandfathered status and must comply with the regulations, but is expected to level off in the next three years. The frequency of response will be on occasion, mirroring the frequency of benefit claims that require responses, totaling about 399 million per year. The hour burden, which will also increase over time as additional plans lose grandfathered status, is estimated to average 774,200 hours over the next three years.

Under PHS Act section 2719, 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 final regulations. These estimates include only ongoing costs of compliance with the statute and the regulations.

Ongoing burdens are a function of claims volume, as well as the denial and appeal rates of plans. Each covered individual was estimated to generate 10.2 claims on average per year,[2] 82 percent of which were filed electronically. The Departments then assumed that 15 percent of these claims were denied.[3]

The Departments assume that three percent of these claims were pre-service with the remaining being post-service claims. The number of post-service claims extended was based on the share of ''clean'' claims that took more than 30 days to complete processing. The share of denials expected to be appealed, 0.2 percent, was based on a RAND study.[4] The Departments expect half of these appeals to be reversed, and those not reversed were divided between ''medical claims'' (28.9 percent) and ''administrative claims'' (71.1 percent).

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

[2] Used previous estimates of 10.2 claims per enrollee to find number of claims and 3% as the share pre-service. Electronic vs. Paper based on AHIP's May 2006 study

[3] Share of denials based on HIAA (now AHIP) March 2003 report on Claims Payment Processes (and EBSA assumptions on appeals)

[4] Share of denials appealed based on RAND 2004 study entitled "Inside the Black Boc of Managed Care Decisions"

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 benefit determinations.

The Departments attributed costs to notifying individuals of denied claims and processing appeals. Initial denials were assumed to only take a few minutes for a clerical worker to draft and send an adverse benefit determination notice based on the model notice that will be issued by the Departments that does not require any information to be included that cannot be auto-populated. Appealed denials deemed "medical"are assumed to require a physician, with an estimated labor rate of $181.07 to review and was expected to take four and a half hours to decide and draft a response, regardless of outcome. Appealed denials deemed "administrative" require a legal professional with an estimated labor rate of $129.94, and a decision and response was expected to take two minutes for a reversal and two hours for a denial. Mailing costs for the notice of adverse determination and notice of decision of internal appeal is estimated at 54 cents a notice for material, printing, and postage costs.

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 1.--*Hour and Cost Burden (in thousands)*

	Claims Government Sector ESI	Claims Individual Marked	In-House Burden Hours	In-House Burden Hours Equivalent Costs	In-House Burden Mailing Costs	Out-House Burden Mailing Cost	Out-House Burden Labor Costs	In and Out House Cost Burden Total Cost Burden
Pre-Service Claim Approved	7,910.7	2,261.2	44.1	$1,341.5	$281.0	$799.3	$3,815.7	$4,895.9
Pre-Service Claim Denied	1,396.0	399.0	15.6	$473.5	$49.6	$141.0	$1,346.7	$1,537.3
Post-Service Claim Denied	45,137.4	12,902.4	503.2	$15,308.7	$1,603.3	$4,560.5	$43,543.7	$49,707.5
Post-Service Claim Extended	11,194.1	4,008.5	75.9	$2,308.3	$483.5	$1,131.0	$5,399.4	$7,013.9
Denial Appeal Total	106.4	38.1	132.4	$22,071.7	$25.5	$59.8	$51,628.7	$51,714.0

	Claims Government Sector ESI	Claims Individual Marked	In-House Burden Hours	In-House Burden Hours Equivalent Costs	In-House Burden Mailing Costs	Out-House Burden Mailing Cost	Out-House Burden Labor Costs	In and Out House Cost Burden Total Cost Burden
Appeal Upheld	42.6	15.2	30.4	$5,490.7	$10.2	$23.9	$12,843.6	$12,877.7
Appeal Denied	63.9	22.9	102.0	$16,580.9	$15.3	$35.9	$38,785.1	$38,836.2
Medical Sub-Total			95.1	$17,218.5	$7.4	--	$40,276.3	$40,283.7
Claim Upheld	12.3	4.4	30.0	$5,437.4	$3.0	--	$12,718.8	$12,721.8
Claim Denied	18.5	6.6	65.1	$11,781.1	$4.4	--	$27,557.5	$27,561.9
Admin Sub Total	75.7	27.1	37.3	$4,853.2	$18.2	--	$11,352.3	$11,370.5
Claim Upheld	30.3	10.8	0.4	$53.3	$7.3	--	$124.8	$132.0
Claim Denied	45.4	16.3	36.9	$4,799.9	$10.9	--	$11,227.6	$11,238.5
Fair and Full Review	74.5	26.7	2.5	$76.8	$13.9	$32.5	$177.2	$223.6
Notice of Decision External Review	1.8	0.2	0.4	$74.8	$0.8	$1.0	$95.3	$106.1
Total	310,223	88,676	774.2	$41,655.2	$2,457.7	$6,725.3	$106,020.5	$115,203.4

Assumed that 7 percent of large plan process these claims in-house in the Group Market. Large plans account for 69.5 percent of policy-holders and therefore 4.9 percent of claims are processed in-house.

* Used previous estimates of 10.2 claims per enrollee to find number of claims and 3% as the share pre-service. Electronic vs. Paper based on AHIP's May 2006 study

** Share of denials based on HIAA (now AHIP) March 2003 report on Claims Payment Processes (and EBSA assumptions on appeals)

*** Share of denials appealed based on RAND 2004 study entitled "Inside the Black Boc of Managed Care Decisions"

**** Share requesting external review and the reversal statistics taken from the January 2006 AHIP report on State External Review Programs

***** Share of claims requiring extension based on the number of claims requiring more than 30 day to process, taken from AHIP January 2010 study "A Survey of Health Care Claims Receipt and Processing Times, 2009."

Non-English Language Assistance

As a result of the May 2011 amendment to the interim final regulations which are now being finalized, plans and issuers must provide participants and beneficiaries who reside in a county where ten percent or more of the population residing in the county is literate only in the same non-English language with 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, plans 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 request.

The Department expects that the largest cost associated with the 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 Department estimates that there are about 8.7 million individuals living in covered counties that are literate only in a non-English Language. The ACS does not have insurance coverage information. Therefore, to estimate the percentage of the 8.7 million affected individuals who were insured, the Departments used the percent of the population in the state that reported being insured by nonfederal government employer insurance from the 2014 CPS.[6] This results in an estimate of approximately 2.1 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 average 0.098 requests per 1,000 members. While the California law is not identical to the federal regulations, and the demographics for California do not match other counties nationally, 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 that there are 12.9 million individuals insured through non-federal governmental employer sponsored insurance or through the individual insurance market living in the affected counties. Based on the foregoing, the Departments estimate that the cost to provide translation services will be approximately $633,000 annually (12,925,000 lives * 0.098/1000 * $500).

[5] Data are from the 2009-2013 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.

External Review Process

This ICR also accounts 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 nonfederal governmental plans have an option of contracting with Independent Review Organizations (IROs) as described in the Department of Labor Technical Release 2010-01.

Both health insurance issuers and self-funded nonfederal 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.

Health insurance issuers and self-funded nonfederal governmental plans that have opted to use either the 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 via the Health Insurance Oversight System (HIOS). If they are using the HHS process, they will also be required to electronically 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 1) the CMS 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; 4) the examiner to forward to the applicable plan or issuer any information submitted by the claimant; 5) that if the applicable plan or issuer reverses its decision, it must notify the claimant and the examiner; 6) the examiner to notify claimant and the applicable plan or issuer of result of final external review (burden previously accounted for); and 7) 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 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; and 6) finally, the IRO must retain its records for six years.

It is estimated that there will be 2,057 external reviews conducted in a year for the affected population.[7]

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 970 with an equivalent cost of $549,400. The Department 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. The Department used salary data provided by the Department of Labor National Occupational Employment Survey.

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

Summary

Total burden hours are estimated at 774,800 hours annually for 2015 and 773,850 hours annually for 2016 and 2017. Equivalent costs are estimated at $41.7 million annually for 2015 and $41.6 million annually for 2016 and 2017.

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 is 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 ($30.42)[8], doctors ($181.07)[9] or lawyers (129.94),[10] and then adding the

[7] Rate of external reviews is 0.013%. AHIP Center for Policy Research, "An Update on State External Review Programs, 2006," July 2008. North Carolina Department of Insurance "Healthcare Review Program: Annual Report," 2013.

[8] Secretaries, Except Legal, Medical, and Executive (43-6014): $16.35(2013 BLS Wage rate)/0.675(ECEC ratio) *1.2(Overhead Load Factor) *1.023(Inflation rate) ^2(Inflated 2 years from base year) = $30.42

[9] Family and General Practitioner (29-1062): $88.43(2013 BLS Wage rate) /0.69(ECEC ratio) *1.35(Overhead Load Factor) *1.023(Inflation rate) ^2(Inflated 2 years from base year) = $181.07

[10] The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics

cost of copying and mailing responses (0.54 each for those not sent electronically)[11]. These costs are described in Table 1 in answer 12.

The total estimated cost burden for those plans that use service providers, including the cost of mailing all responses (including mailing costs for those prepared in-house listed in Table 1), is $115.8 million annually.

Federal External Review Process

It is estimated that there will be an administrative cost burden of $18,000 on average over the next three years associated with the Federal external review process. This administrative cost burden is a result of sending the files and notices required by the proposal to the independent examiner for health insurance issuers and self-funded nonfederal governmental health plans using the HHS process.

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. It is expected to average $504,045 over the next three years. This burden includes contract costs as well as the cost for oversight and contract management of the HHS federal external review program.

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

One of the critical components of the original burden estimates was the number of plans expected to lose grandfathered status. These estimates have been updated based on more recent Medical Loss Ratio (MLR) data. There is nearly double the original estimate of non-grandfathered plans now subject to the Appeals regulation. Changes in the estimates for external review costs and the rate of external review requests also impacted the expected burden. The hour and cost burdens have been updated based on improved estimates of the costs associated with external review and the rate of external review. For example, the external review rate used to determine the expected number of external reviews was .03%. This rate was based on the Office of Personnel Management's experience in operating the Federal Employee Health Benefit Plan (FEHBP). However, since OPM is no longer administering the HHS Federal External Review Program, we have updated our rate

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http://www.bls.gov/news.release/pdf/ocwage.pdf); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics http://www.bls.gov/news.release/ecec.t02.htm); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 http://www.bls.gov/news.release/eci.nr0.htm).

[11] $0.49 for USPS First Class Postage and $0.05 per page of materials costs for two pages of paper.

based on what state external review experience, such as data from the state of North Carolina. It is believed that this new rate is a more accurate reflection of the rate at which consumers request external reviews. Based on these adjustments, the estimated annual responses have increased from 218,657,161 to 399,154,868.

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.