

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.*

Section 503 (“the Claims Procedure”) of ERISA states, in its entirety:

In accordance with regulations of the Secretary, every employee benefit plan shall --

- (1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for the denial, written in a manner calculated to be understood by the participant, and
- (2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claims.

In November, 2000, the Department issued a final regulation establishing minimum claims procedure requirements that all employee benefit plans under ERISA must meet in order to satisfy the requirements of section 503.¹ The claims procedure regulation is codified at 29 CFR 2560.503-1. Section 505 of ERISA authorizes the Secretary to prescribe regulations as appropriate or necessary to carry out the provisions of Title I of ERISA. The 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 regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions.

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.

2016 Amendments to Disability Claims Procedure Rules

The Department is amending the current procedural protections for workers who become disabled and make claims for disability benefits from an employee benefit plan. ERISA requires

¹ The claims procedure regulation replaced an earlier regulation that had been issued in 1977.

that plans provide claimants with written notice of benefit denials and an opportunity for a full and fair review of the denial by an appropriate plan fiduciary. The current regulations governing the processing of claims and appeals were published 15 years ago. Because of the volume and constancy of litigation in this area, and in light of advancements in claims processing technology, the Department recognizes a need to revisit, reexamine, and revise the current regulations in order to ensure that disability benefit claimants receive a fair review of denied claims as provided by law. To this end, the Department has determined to uplift the current standards applicable to the processing of claims and appeals for disability benefits so that they better align with the requirements regarding internal claims and appeals for group health plans under the regulations implementing the requirements of the Affordable Care Act.² Inasmuch as disability and lost earnings can be sources of severe hardship for many individuals, the Department believes that disability benefit claimants deserve protections equally as stringent as those that Congress and the President have put into place for health care claimants under the Affordable Care Act.

The major provisions largely adapt the procedural protections for health care claimants in the Affordable Care Act, including provisions that seek to ensure that: (1) claims and appeals are adjudicated in manner designed to ensure independence and impartiality of the persons involved in making the decision; (2) benefit denial notices contain a full discussion of why the plan denied the claim and the standards behind the decision; (3) claimants have access to their entire claim file and are allowed to present evidence and testimony during the review process; (4) claimants are notified of and have an opportunity to respond to any new evidence reasonably in advance of an appeal decision; (5) final denials at the appeals stage are not based on new or additional rationales unless claimants first are given notice and a fair opportunity to respond; (6) if plans do not strictly adhere to all claims processing rules, the claimant is deemed to have exhausted the administrative remedies available under the plan, unless the violation was the result of a minor error and other specified conditions are met; (7) certain rescissions of coverage are treated as adverse benefit determinations, thereby triggering the plan's appeals procedures; and (8) notices are written in a culturally and linguistically appropriate manner.

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

² The Patient Protection and Affordable Care Act, Public Law 111-148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, was enacted on March 30, 2010. (These statutes are collectively known as the "Affordable Care Act.")

beneficiaries need to understand plan procedures and plan decisions in order to appropriately request benefits and/or appeal benefit denials.

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 does 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 regulation incorporates by reference the pertinent provisions of the Department's separate regulation, 29 CFR 2520.104b-1, which facilitates and encourages the use of electronic information technology. This burden estimate incorporates the Department's assumptions, described in the response to item 12, below, concerning the rate of use by plans 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 (small business, small plans) that provide benefits. 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. Every claim event is normally of importance to the specific participant who relies on an employee benefit plan to provide the promised benefit. The information collection provisions of the regulation ensure that sufficient information is provided to: a) participants and beneficiaries so that they may fully exercise their rights under their employee benefit plans, and b) to fiduciaries responsible for operating plans in accordance with their terms.

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 regulation imposes special timing requirements for the handling of claims under group health plans. Depending on circumstances indicating the urgency of the need for a claims decision, group health plans 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.

These timing requirements are reasonably 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, payors could be given a financial incentive to delay the payments, and this would likely be inconsistent with appropriate fiduciary standards. Finally, these time frames for health and disability claims are generally consistent with industry standards and with the requirements of other regulators such as state insurance departments.

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 Department published the required 60-day notice soliciting comments on the information collection on the Notice of Proposed Rulemaking published in the Federal Register on November 18, 2015 (80 FR 72014, 72025).. In response, the Department received 145 comments. Responses to all comments are discussed in the preamble of the final rule. Eight commenters submitted comments directed specifically at the Department's cost estimates for the proposed rule. These comments are addressed below.

Based on comments and discussions with the regulated community, the Department understands that few appeals based adverse benefit determinations on new evidence or rationale. The Department also understands that the most critical new information relied on by plans when issuing adverse benefit determinations on review are new independent medical reports, and that at least some plans and insurers have a practice of providing claimants with rights to a second appeal to respond to the new independent medical report if they disagree with its findings.

One commenter questioned the Department's assumption asserting that it does not account for time to identify the additional or new information or rationale and for staff to respond. Commenters also asserted that providing the information will trigger a response by the claimant to which they will have to respond. The commenter provided no alternative estimates or data supporting their assertions that the Department could use to revise its cost estimate.

In the absence of such data, the Department disagrees with the comment. While some effort is required to provide claimants with the new information or rationale, the Department does not find the commenter's assertion of significant burden to be credible. As part of its customary and usual business practices, the insurer or TPA should establish a system to track new information or a rationale that it relies on in making an adverse benefit determination in order to identify, document, and evaluate the information during its review of the claim. The Department acknowledges, however, that an average of five minutes may be inadequate time to collect the information and provide it to the claimants; therefore, it has increased the estimate to an average of 30 minutes, which should provide a reasonable amount of time to perform this task.

The Department also agrees that making the new or additional information or rationale available to the claimant may trigger a response from the claimant. However, the Department does not have sufficient data to estimate the number of claimants that will respond with information that the insurer or TPA will need to evaluate or how much time will be required to evaluate the information. Moreover, the Department's consultations with EBSA field investigators that investigate disability plan issues indicate that many disability plans already allow claimants to respond to the new information or rationale in a back-and-forth process. The requirement imposes no new costs on these plans, insurers, and TPAs. The requirement does impose an additional burden on plans that do not allow claimants to respond to the new information or rationale, but the Department does not have sufficient data to estimate the increased costs. One industry commenter agreed that that it would be difficult to estimate the burden associated with responding to claimants.

Commenters also raised concern regarding a potentially endless cycle of appeals, responses, and reconsiderations that would extend the claim determination process and substantially increase costs. As discussed in the preamble, the Department also does not find this claim to be credible. The requirement only requires action if the insurer or TPA produces new or additional information or rationale, not if it just evaluates the information submitted by the claimant, and the Department's consultations with its investigators indicated that this rarely occurs. Furthermore, the Department has interpreted ERISA section 503 and the current Section 503 Regulation as already requiring that plans provide claimants with new or additional evidence or rationales upon request and an opportunity to respond in certain circumstances. See Brief of amicus curiae Secretary of the United States Department of Labor, *Midgett v. Washington Group International Long Term Disability Plan*, 561 F.3d 887 (8th Cir. 2009) (expressing disagreement with cases holding that there is no such requirement). The supposed "endless loop" is necessarily limited by claimants' ability to generate new evidence requiring further review by the plan. Such submissions ordinarily become repetitive in short order, and are further circumscribed by the limited financial resources of most claimants.

Adverse benefit determinations on disability benefit claims would have to contain a discussion of the decision, including the basis for disagreeing with SSA Disability Determination and Views of Treating Physician: Commenters on the proposal noted that costs were not quantified for the added burden of including in the benefit determination a discussion of why the plan did not follow the determination of the Social Security Administration (SSA) or views of health care professionals that treated the claimant. Commenters did not provide data or information that would provide the Department with sufficient data to quantify such costs. Thus, while the Department agrees that there could be added burden imposed on plans to provide this discussion in adverse benefit determinations, the Department is unable to estimate the burden due to data limitations.

Adverse benefit determination would have to contain the internal rules, guidelines, protocols, standards, or other similar criteria of the plan used in denying the claim. The Department believes that this requirement will have minimal costs. In the process of determining a claim, plans will know, or should know, the internal rules, guidelines or protocols that were used to make a benefit determination. A commenter was concerned about the time and costs that would be required to comb through hundreds of pages of a claim manual to determine that no provision has any conceivable application to a particular claim in order to substantiate this requirement. The Department believes that neither the proposal nor the final rule requires this type of costly and time consuming process. The rule requires only the inclusion of those items that were relied upon and that should already be documented in the claim file at the time it was used to make a determination.

Culturally and Linguistically Appropriate Notices:

Although, one commenter reported that oral translation services are not provided by plans, the Department's conversations with the regulated community indicate that oral translation services generally are offered as a standard service. Based on this information, the Department assumes that only a small number of plans will need to begin offering oral translation services for the first time upon the issuance of the final rule. Therefore, the Department assumes that this requirement will impose minimal additional costs.

Commenters questioned the data the Department used in the regulatory impact analysis for the proposed rule to estimate the costs incurred by TPAs and insurers to provide culturally and linguistically appropriate notices. One commenter questioned whether the \$500 per document translation cost accurately reflects the costs to comply with this provision. The commenter, however, failed to explain its rationale or provide any alternative information the Department could use to refine its estimate.

Another commenter questioned whether it was valid to rely on cost estimates to translate a notice into a non-English language based on data used by the Department to quantify the costs of complying with the a similar ACA requirement for group health plans. The Department believes that its experience with ACA group health plan claims and appeals regulations is directly applicable to this final regulation regarding disability claims and appeals. Contrary to the commenter's assertion that disability claims are so different from health claims that information about one cannot inform the other, the Department believes that translation of a notice into a different language is very similar for health and disability benefits, particularly as the same translation companies offer services for both types of notices.

In the Department's view, the preamble statement is an accurate example of one way that the independence and impartiality standard would be violated, and, accordingly, does not believe it would be appropriate to disclaim or caveat the statement in the final rule. That said, the

independence and impartiality requirements in the rule do not modify the scope of what would

Deemed Exhaustion of Claims and Appeals Process: Commenter's raised concern the claimants would be hurt by the higher costs and delay in obtaining a resolution if they sought resolution through litigation. However, this provision allows claimants to decide if the added costs and time of litigation are offset by the cost to them of remaining in an appeals process that is in violation of the procedural rules.

Some commenters maintained that their liability exposure increases when claimants' ability to go to court is enhanced. These commenters expressed concern about the expense of discovery to even determine if the procedural requirements have not been followed and claimants will allege that plans have violated their procedures and go to court to force a settlement.

While all of these scenarios are possible, the Department does not know of, nor did commenters provide, any data or information that would even be suggestive of, the frequency of these events, or the added expense resulting from their occurrence. The Department is not aware, of systematic abuses, or complaints of abuse with respect to a similar deemed exhaustion requirement contained in the Departments group health plan regulation. Thus, the Department believes these occurrences will be infrequent.

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 plan administrators to plan participants. 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 information collection provisions of the regulation are found in 29 CFR 2560.503-1 (g), (h), (i), and (j), and in ERISA at section 503. The Department estimates that this information collection affects 5,808,000 respondents. The frequency of response will be on occasion, mirroring the frequency of benefit claims that require responses, totaling about 311,790,000 per year. The hour burden is estimated to be 516,000 hours annually while the cost burden is estimated to be \$814,450,000.

The Department’s final regulation governing ERISA plans’ claims procedures, of which this information collection is part, generally became applicable on or after January 1, 2003. The 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 various plans. As shown in the table below, health benefit claims comprise the majority of all claims filed annually.

TABLE 1.--*Claims (in thousands)*

	Health	Disability		Pension	Other	Total
		Short-Term	Long-Term			
Claims	1,328,040	2,850	715	2,078	305	1,333,988
Pre-Service						
Claim Approved	33,865.0	--	--	--	--	33,865
Claim Denied	5,976.2	--	--	--	--	5,976
Post-Service						

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	193,229.					
Claim Denied	8	85.5	536.4	18.1	9.1	193,879
Claim Extended	77,291.9	28.5	143.0	0.0	0.0	77,463
Denial Appeal						
Total	455.7	8.6	137.3	1.8	0.9	604
Appeal Approved	182.3	4.3	13.7	0.9	0.5	202
Appeal Denied	273.4	4.3	13.7	0.9	0.5	293
Medical*	131.7	--	--	--	--	132
Claim Approved	52.7	--	--	--	--	53
Claim Denied	79.0	--	--	--	--	79
Administrative	324.0	--	--	--	--	324
Claim Approved	129.6	--	--	--	--	130
Claim Denied	194.4	--	--	--	--	194
Total Responses	310,819	123	817	20	10	311,788

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 six hours for certain disclosures on request following adverse claim determinations.

The Department estimates that approximately 93 percent of large benefit and all small benefit plans administer claims using a third-party provider. An estimated 9,842 health, 6,137 disability, 6,035 pension and 8,916 other plans administer claims 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)

	Health	Disability		Pension	Other	Mailing Cost	Total Hours
		Short-Term	Long-Term				
Pre-Service							
Claim Approved	27.5	--	--	--	--	\$235	27.5
Claim Denied	9.7	--	--	--	--	\$42	9.7
Post-Service							
Claim Denied	314.3	2.1	26.2	0.1	0.0	\$5,392	342.7
Claim Extended	62.9	0.3	3.5	0.0	0.0	\$2,155	66.7
Denial Appeal							
Total	68.0	0.2	1.4	0.0	0.0	\$17	69.6
Appeal Approved	15.6	0.0	0.0	0.0	0.0	\$6	15.7

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Appeal Denied	52.4	0.2	1.3	0.0	0.0	\$8	53.9
Medical	48.8	--	--	--	--	\$4	48.8
Claim Approved	15.4	--	--	--	--	\$1	15.4
Claim Denied	33.4	--	--	--	--	\$2	33.4
Administrative	19.2	--	--	--	--	\$9	19.2
Claim Approved	0.2	--	--	--	--	\$4	0.2
Claim Denied	19.0	--	--	--	--	\$5	19.0
Total	482	3	31	0	0	\$7,841	516.2

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

Total burden hours are estimated at 516,200 hours. Using the hourly cost of clerical workers (\$54.74), doctors (\$157.80) or legal professionals (133.50),³ as appropriate, the equivalent costs are estimated to be \$56,285,200.

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 these 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 from question 12, and then adding the cost of copying and mailing responses (0.57 each for those not sent electronically). These costs are described below:

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

	Health	Disability		Pension	Other	Mailing Cost	Total Costs
		Short-Term	Long-Term				
Pre-Service							
Claim Approved	\$29,389	--	--	--	--	\$4,590	\$33,979
Claim Denied	\$10,372	--	--	--	--	\$810	\$11,182
Post-Service							
Claim Denied	\$335,376	\$6,417	\$80,508	\$79	\$40	\$27,905	\$450,325
Claim Extended	\$67,075	\$1,070	\$10,734	\$0	\$0	\$11,112	\$89,991
Denial Appeal							
Total	\$200,156	\$649	\$4,146	\$20	\$10	\$344	\$205,326
Appeal Approved	\$47,991	\$7	\$24	\$1	\$0	\$115	\$48,139
Appeal Denied	\$152,165	\$642	\$4,122	\$19	\$10	\$167	\$157,124

³ For a description of the Department's methodology for calculating wage rates, see <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-august-2016.pdf>

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Medical	\$150,235	--	--	--	--	--	\$150,235
Claim Approved	\$47,443	--	--	--	--	--	\$47,443
Claim Denied	\$102,792	--	--	--	--	--	\$102,792
Administrative	\$49,921	--	--	--	--	--	\$49,921
Claim Approved	\$549	--	--	--	--	--	\$549
Claim Denied	\$49,373	--	--	--	--	--	\$49,373
Total Costs	\$642,368	\$8,136	\$95,389	\$99	\$50	\$44,762	\$790,803

Note: Assumed that 93 percent of large plans and all small plans process these claims in-house. This results in 95.3 percent of claims being processed out-house

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 2), is \$798,644,000 annually (\$790,803,000 + \$7,841,000).

2016 Amendments

Provision of new or additional evidence or rationale: Before a plan providing disability benefits can issue an adverse benefit determination on review on a disability benefit claim, these final regulations require such plans to provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan or any new or additional rationale upon which the adverse determination is based as soon as possible and sufficiently in advance of the date the notice of adverse benefit determination on review is required to be provided. This requirement may increase the administrative burden on plans to prepare and deliver the enhanced information to claimants. The Department is not aware of a data source substantiating how often plans rely on new or additional evidence or rationale during the appeals process or the volume of materials that comprise the new evidence or rationale. Based on comments and discussions with the regulated community, the Department understands that few plans base adverse benefit determinations on appeal on new evidence or rationales. The Department also understands that the most critical new information relied on by plans when issuing adverse benefit determinations on review are new independent medical reports, and that at least some plans and insurers have a practice of providing claimants with rights to a voluntary additional level of appeal to respond to the new independent medical report if they disagree with its findings.

For purposes of this analysis, the Department assumes, as an upper bound, that all appealed claims will involve a reliance on additional evidence or rationale. Based on that assumption, the Department assumes that this requirement will impose an annual aggregate cost of \$14.5 million as shown in Table 4. The method for estimating the number of effected claims is also discussed below.

The Department estimates this cost by assuming that compliance will require medical

office staff, or another service providers' similar staff with a labor rate of \$42.08, thirty minutes to collect and distribute the additional evidence considered, relied upon, or generated by (or at the direction of) the plan during the appeals process.⁴ The Department estimates that on average, material, printing and postage costs will total \$2.15 per mailing (20 pages * 0.05 cents per copy + \$1.15 postage). The Department further assumes that 30 percent of all mailings will be distributed electronically with no associated material, printing or postage costs.⁵

These final rules further require adverse benefit determinations on review for disability benefit plans to include a description of any contractual limitations period, including the date by which the claimant must bring a lawsuit. Including a description of any contractual limitations period, including the date by which the claimant must bring a lawsuit would have minimal additional burden as plans already maintain such information in the ordinary course of their claims administration process and would just need to add it to the notice.

The Department agrees with commenters that making the new or additional information or rationale available to the claimant may trigger a response from the claimant. However, the Department does not have sufficient data to estimate the number of claimants that will respond with information that the insurer or TPA will need to evaluate or how much time will be required to evaluate the information. Moreover, the Department's consultations with EBSA field investigators that investigate disability plan issues indicate that many disability plans already allow claimants to respond to the new information or rationale in a back-and-forth process. The requirement imposes no new costs on these plans, insurers, and TPAs. The requirement does impose an additional burden on plans that do not allow claimants to respond to the new information or rationale, but the Department does not have sufficient data to estimate the increased costs. One industry commenter agreed that that it would be difficult to estimate the burden associated with responding to claimants.

Commenters also raised concern regarding a potentially endless cycle of appeals, responses, and reconsiderations that would extend the claim determination process and substantially increase costs. The Department also does not find this claim to be credible. The requirement only requires action if the insurer or TPA produces new or additional information or

⁴ For a description of the Department's methodology for calculating wage rates, see <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-august-2016.pdf>

⁵ Commenters disagreed in general with the estimates of the burden for providing the notice in a culturally and linguistically appropriate manner. Their concern was that most notices would be delivered on paper and not electronically. While one commenter did not provide any supporting evidence for this assertion, another commenter reported that a large company's past experience was that 30 percent of the claims filed under its disability plan were electronic. For purposes of this regulatory impact analysis, the Department accepted the suggestion posited in the comment that a significant percentage of disability benefit claimants are at home without access to an electronic means of communication at work that is required by the Department's electronic disclosure rule. Therefore, the Department assumes that a higher percentage of notices will be transmitted via mail even though data was provided only for a single company.

rationale after reviewing the new information submitted by the claimant, not if it just evaluates the information submitted by the claimant, and the Department's consultations with its investigators indicated that this occurs infrequently.

Additionally, while a plan fiduciary has a responsibility to ensure the accurate evaluation of all claims, that responsibility does not require the fiduciary to rebut every piece of evidence submitted or seek to deny every claim. Indeed, an endless effort to rebut every piece of evidence submitted by the claimant would call into question whether the fiduciary was impartially resolving claims as required by the duties of prudence and loyalty.

Furthermore, the Department has interpreted ERISA section 503 and the current Section 503 Regulation as already requiring that plans provide claimants with new or additional evidence or rationales upon request and an opportunity to respond in certain circumstances. See Brief of the Secretary of Labor, Hilda L. Solis, as Amicus Curiae in Support of Plaintiff-Appellant's Petition for Rehearing, Midgett v. Washington Group Int'l Long Term Disability Plan, 561 F.3d 887 (8th Cir. 2009) (No. 08-2523), (expressing disagreement with cases holding that there is no such requirement). The supposed "endless loop" is necessarily limited by claimants' ability to generate new evidence requiring further review by the plan. Such submissions ordinarily become repetitive in short order, and are further circumscribed by the limited financial resources of most claimants.

The Department does not have an available data set to directly estimate the number of disability claims that are filed or denied. Therefore, the Department estimates the number of short- and long-term disability claims based on the percentage of private sector employees (122 million)⁶ that participate in short- and long-term disability programs (approximately 39 and 33 percent respectively).⁷ The Department estimates the number of claims per covered life for long-term disability benefits based on the percentage of covered individuals that file claims under the Social Security Disability Insurance Program (SSDI) (two percent of covered individuals). The Department notes that SSDI uses a standard for disability determinations that is stricter than the standard used in many long-term disability plans offered by private employers. However, the number of claims filed with the SSDI is an acceptable proxy as most employer plans require claimants to file with the SSDI as a condition of receiving benefits from the plan as they offset the benefits paid by plan with the amount received from SSDI.

The Department does not have sufficient data to estimate the percentage of covered individuals that file short-term disability claims. Therefore, for purposes of this analysis, the

⁶ BLS Employment, Hours, and Earnings from the Current Employment Statistics survey (National) Table B-1, May 2016. It should be noted that this estimate differs from the estimates from the Form 5500 reported in the affected entities section. The Form 55000 numbers only include large plans, and some filings could combine estimates for both short and long term disability.

⁷ "Beyond the Numbers: Disability Insurance Plans Trends in Employee Access and Employer Cost," February 2015 Vol. 4 No. 4. <http://www.bls.gov/opub/btn/volume-4/disability-insurance-plans.htm>.

Department estimates, as it did in the proposal, that six percent of covered lives file such claims, because it believes that short-term disability claims rates are higher than long-term disability claim rates. The Department received no comments regarding this assumption.

The Department estimates the number of denied claims that would be covered by the rule in the following manner: For long-term disability, the percent of claims denied is estimated using the percent of denied claims for the SSDI Program (75 percent). This estimate may overstate the denial rates for ERISA-covered long-term disability plans, because as discussed above, many plans require claimants to file for SSDI benefits as a requirement to receive benefits from their plan. Plans often have a lower benefit determination standard, at least initially, than the SSDI Program resulting in less denied claims. Therefore, using the SSDI denied claims rate as a proxy for the ERISA-covered plan claims denial rate may overstate the number of private long-term disability plan denied claims. For short-term disability, the estimate of denied claims (three percent) is an assumption based on previous regulations and feedback. The estimates are provided in the table below.

Table 4.--Fair and Full Review Burden (in thousands)

	Short-Term		Long-Term		Total		
	Electroni c	Paper	Electroni c	Paper	Electroni c	Paper	All
Denied Claims and lost Appeals with Additional Information	26	60	168	391	193	451	644
Mailing cost per event	\$0.00	\$2.15	\$0.00	\$2.15	\$0.00	\$2.15	
Total Mailing Cost	\$0.00	\$129	\$0.00	\$841	\$0.00	\$969	\$969
Preparation Cost per event	\$21.04	\$21.04	\$21.04	\$21.04	\$21.04	\$21.04	\$21.04
Total Preparation cost	\$540	\$1,260	\$3,526	\$8,227	\$4,066	\$9,487	\$13,553
Total	\$540	\$1,388	\$3,526	\$9,068	\$4,066	\$10,456	\$14,522

Adverse benefit determinations on disability benefit claims would have to contain a discussion of the decision, including the basis for disagreeing with SSA Disability Determination and Views of Treating Physician: Commenters on the proposal noted that costs were not quantified for the added burden of including in the benefit determination a discussion of why the plan did not follow the determination of the SSA or views of health care professionals that treated the claimant. Commenters did not provide data or information that would provide the Department with sufficient data to quantify such costs. Thus, while the Department agrees that

there could be added burden imposed on plans to provide this discussion in adverse benefit determinations, the Department is unable to estimate the burden because it does not have sufficient data on the number or percent of claims that would need to contain this discussion.

Departmental investigators reviewing disability claims report that if the plan deviates from an attending physician's recommendation, a review is conducted by a supervisor, nurse, medical director or a consultant. This additional review usually generates documentation in the claim file. While this documentation may not be adequate in its current form to satisfy the requirement, the incremental costs to comply could be small, because it appears that deviations from physician's recommendations are documented currently. Plans or insurers may still need to prepare a response using the already available information. The Department does not know how many claim determinations would require this discussion. The average hourly labor rate of a nurse is \$46.02 and that of a physician is \$157.80, and the Department estimates that preparing a report with information already available should not take more than one hour.

Adverse benefit determination would have to contain the internal rules, guidelines, protocols, standards, or other similar criteria of the plan used in denying the claim. The Department believes that this requirement will have minimal costs. In the process of determining a claim, plans will know, or should know, the internal rules, guidelines or protocols that were used to make a benefit determination. A commenter was concerned about the time and costs that would be required to comb through hundreds of pages of a claim manual to determine that no provision has any conceivable application to a particular claim in order to substantiate this requirement. The Department believes that neither the proposal nor the final rule requires this type of costly and time consuming process. The rule requires only the inclusion of those items that were relied upon and that should already be documented in the claim file at the time it was used to make a determination.

A notice of adverse benefit determination at the claims stage would have to contain a statement that the claimant is entitled to receive relevant documents upon request. The Department believes that this requirement will have a negligible cost impact, because an insignificant amount of time will be required to add the statement to the notice. Although the current claims procedure regulation provides claimants with the right to request relevant documents when challenging an initial claims denial, a statement was required to be included only in notices of adverse benefit determinations on appeal. Including the statement in the initial denial notice as required by the final rule, in the Department's view, merely confirms claimants' rights under the current claims procedure regulation and will help ensure that they understand their right to receive such information to help them understand the reasons for the denial and to make informed decisions regarding whether and how they challenge a denial on appeal. The Department acknowledges that it is likely that more claimants will request this information when they are informed of their right to receive it; however, the Department does not have sufficient data to estimate the number of requests that will be made.

Culturally and Linguistically Appropriate Notices: The final regulations require notices of adverse benefit determinations with respect to disability benefits to be provided in a culturally and linguistically appropriate manner in certain situations. This requirement is satisfied if plans provide oral language services including answering questions and providing assistance with filing claims and appeals in any applicable non-English language. The final regulations also require each notice sent by a plan to which the requirement applies to include a one-sentence statement in the relevant non-English language that translation services are available. The Department believes that this requirement will have a negligible cost impact. Plans also must provide, upon request, a notice in any applicable non-English language.

Although, one commenter reported that oral translation services are not provided by plans, the Department's conversations with the regulated community indicate that oral translation services generally are offered as a standard service. Based on this information, the Department assumes that only a small number of plans will need to begin offering oral translation services for the first time upon the issuance of the final rule. Therefore, the Department assumes that this requirement will impose minimal additional costs.

The Department expects that the largest cost associated with the requirement is for plans to provide notices in the applicable non-English language upon request. Based on 2014 ACS data, the Department estimates that there are about 22.7 million individuals living in covered counties that are literate only in a covered non-English Language.⁸ To estimate the number of these individuals that might request a notice in a non-English language, the Department estimated the number of workers in each county (total population in county * state labor force participation rate * (1 – state unemployment rate))^{9,10} and calculated the number with access to short-term and long-term disability insurance by multiplying those estimates by the estimates of the share of workers participating in disability benefit programs (39 percent for short-term and 33 percent for long term disability.)¹¹ It should be noted that the sums in the right two columns are all workers in the county with disability insurance, not just workers with disability insurance that are eligible to receive notices in the applicable non-English language, because the calculation for the number of requests for translation is based on workers with insurance.

8 <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data.pdf>
<http://www.dol.gov/ebsa/pdf/coveragebulletin2014.pdf> Table 1C.

9 Labor force Participation rate: <http://www.bls.gov/lau/staadata.txt> Unemployment rate:
<http://www.bls.gov/lau/lastrk14.htm>.

10 Please note that using state estimates of labor participation rates and unemployment rates could lead to an over estimate as those reporting in the ACS survey that they speak English less than “very well” are less likely to be employed. Also, this estimate includes both private and public workers, instead of just private workers leading to an overestimate of the costs.

11 "Beyond the Numbers: Disability Insurance Plans Trends in Employee Access and Employer Cost," February 2015 Vol. 4 No. 4. <http://www.bls.gov/opub/btn/volume-4/disability-insurance-plans.htm>.

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TABLE 5.--Workers in Affected Counties by State

	Pop in the County	Total Affected Foreign Language Pop in County	State Labor Force Participation Rate (2015)	State Unemployment Rate (2015)	Workers With Short-Term Disability Coverage	Workers With Long-Term Disability Coverage
Alabama	29,519	3,979	56%	6%	6,097	5,159
Alaska	8,634	2,677	67.1%	6.5%	2,113	1,788
Arizona	296,362	160,492	59.8%	6.1%	64,901	54,917
Arkansas	15,864	4,598	57.9%	5.2%	3,396	2,874
California	26,248,619	8,845,211	62.2%	6.2%	5,972,612	5,053,748
Colorado	513,177	122,183	66.7%	3.9%	128,287	108,550
Florida	3,166,261	1,785,759	59.3%	5.4%	692,719	586,147
Georgia	284,282	72,578	61.3%	5.9%	63,953	54,114
Idaho	87,012	21,145	63.9%	4.1%	20,795	17,596
Illinois	484,509	126,443	64.7%	5.9%	115,043	97,344
Iowa	35,029	7,861	69.9%	3.7%	9,196	7,781
Kansas	254,997	72,446	67.9%	4.2%	64,690	54,737
Missouri	6,170	919	65.6%	5.0%	1,500	1,269
Nebraska	106,532	26,134	70.1%	3.0%	28,251	23,905
Nevada	1,869,086	431,029	63.2%	6.7%	429,826	363,699
New Jersey	1,736,310	563,516	64.1%	5.6%	409,753	346,714
New Mexico	512,864	218,554	57.2%	6.6%	106,859	90,419
New York	4,983,647	1,472,029	61.1%	5.3%	1,124,613	951,596
North Carolina	55,317	10,260	61.2%	5.7%	12,450	10,535
Oklahoma	23,150	7,325	61.9%	4.2%	5,354	4,530

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Oregon	31,532	8,897	61.1%	5.7%	7,0	5,9
					85	95
Texas	12,541,167	5,304,121	63.7%	4.5%	2,975,4	2,517,6
					00	46
Virginia	50,989	15,060	65.2%	4.4%	12,3	10,4
					95	88
Washington	437,583	164,140	63.0%	5.7%	101,3	85,7
					86	88
Puerto Rico	3,433,930	3,252,314	39.8%	11.2%	473,3	400,4
					17	99
Total	57,212,542	22,699,670			12,825,893	10,852,679

The Department's discussions with the regulated community indicate that in California, which has a State law requirement for providing translation services for health benefit claims, requests for translations of written documents averages 0.098 requests per 1,000 members (note that requirement applies to all members not just foreign language speaking) for health claims. While the requirements of California differ from those contained in these final regulations and the demographics for California do not match those of covered counties, for purposes of this analysis, the Department used this percentage to estimate the number of translation service requests that plans could expect to receive. The Department believes that this estimate significantly overstates the number of translation requests that will be received, because there are fewer disability claims than health claims. Industry experts also told the Department that while the cost of translation services varies, \$500 per document is a reasonable approximation of translation cost, and the Department used this amount in its cost estimate for the final rule. This number was provided to the Department in 2010; therefore, for purposes of this analysis, the Department has adjusted this amount to \$553 to account for inflation.¹²

Based on the foregoing, the Department estimates that the cost to provide translation services pursuant to the final rule will be approximately \$1,283,840 annually (23,678,572 lives * 0.098/1000 * \$553).

The Department did not have sufficient data to quantify other costs associated with the final rule; and therefore, has provided a qualitative discussion of these costs below and a response to cost-related comments received in response to the regulatory impact analysis for the proposed regulation.

Deemed Exhaustion of Claims and Appeals Process: The final rule provides that if a plan fails to adhere to all the requirements in the claims procedure regulation, the claimant would be deemed to have exhausted administrative remedies, with a limited exception where the

¹² The 2010 and 2016 GDP Deflator was 100.056 in 2010 and 110.714 in 2016. The adjustment is $\$500 * (110.714 / 100.056) = \553 <https://fred.stlouisfed.org/series/GNPDEF>

violation was (i) *de minimis*; (ii) non-prejudicial; (iii) attributable to good cause or matters beyond the plan's control; (iv) in the context of an ongoing good-faith exchange of information; and (v) not reflective of a pattern or practice of non-compliance. Claimants may request a written explanation of the violation from the plan, and the plan must provide such explanation within 10 days. The Department does not know the number of claims where this requirement is applicable, but it is believed to be rare.

The total estimated cost burden is \$814,449,900. These costs includes the costs from table 2 for mailing notices prepared in-house, \$7,841,000; the cost from table 3 for those plans that use service providers, \$790,803,000; the cost of the requirements of a fair and full review, \$14,522,000; and the costs of the requirement for culturally and linguistically appropriate notices, \$1,283,840.

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.*

There are no costs to the Federal government associated with this information collection.

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

As discussed in Item 1, above, with the implementation of the Affordable Care Act, claims regulations participants of disability plans were receiving fewer procedural protections than participants in group health plans, while at the same time experiencing similar if not significantly more issues with the claims review process. These final regulations would reduce the inconsistent claims processes applied to health and disability plans and provide similar procedural protections to both groups of plan participants.

Changes in estimates since the most recent ICR renewal reflect changes to the disability claims part of the regulations (increase of 2,321 burden hours, and \$15,805,959), and increases in hour burden and costs burden due to updated estimates including labor rates, the percent of long term disability claims denied, the percent of disability claims sent electronically (decrease from 75 percent to 30 percent), and the number of health and welfare plans.

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.*

Not applicable.

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.