SUPPORTING STATEMENT Internal Revenue Service

OMB Control Number 1545-2182 Affordable Care Act Internal Claims and Appeals and External Review Procedure for ERISA Plans

1. CIRCUMSTANCES NECESSITATING COLLECTION OF INFORMATION

The Patient Protection and Affordable Care Act, Public Law 111-148, (the Affordable Care Act or the Act) was enacted on March 23, 2010. As part of the Act, Congress added Public Health Service Act (the PHS Act) section 2719, which provides rules relating to internal claims and appeals and external review processes. The Departments issued final regulations (80 FR 72191) that set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503-1 (the Department of Labor's (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.

The DOL claims procedure regulation requires plans to provide every claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The 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. Paragraph (b)(2)(ii)(C) of the final regulations adds a 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

Also, PHS Act section 2719 and the final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. The regulations provide a basis for determining when plans and issuers must comply with an applicable State external review process and when they must comply with the Federal external review process.

The No Surprises Act of 2020 extends the balance billing protection related to external reviews to grandfathered plans. The definitions of group health plan and health insurance issuer that are

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

cited in section 110 of the No Surprises Act include both grandfathered and non-grandfathered plans and coverage. Accordingly, the practical effect of section 110 of the No Surprises Act is that grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections.

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.

TD 9494, address the requirements regarding internal claims and appeals and external review processes for group health plans and health insurance coverage in the group and individual markets under the Patient Protection and Affordable Care Act.

2. USE OF DATA

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.

This is a third-party disclosure requirement. Individuals appealing a denial of a claim should be able to respond to any new evidence the plan or issuer relies on in the appeal, and this disclosure requirement is essential so that the claimant knows of the new evidence.

3. USE OF IMPROVED 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.

4. EFFORTS TO IDENTIFY DUPLICATION

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. <u>METHODS TO MINIMIZE BURDEN ON SMALL BUSINESSES OR OTHER</u> SMALL ENTITIES

The regulation applies to all employee benefit plans and therefore is likely to affect small entities (small business, small plans) that provide benefits. The Departments and Agency 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 Agency 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 infrastructure cost for this information collection 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. <u>CONSEQUENCES OF LESS FREQUENT COLLECTION ON FEDERAL PROGRAMS OR POLICY ACTIVITIES</u>

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) fiduciaries responsible for operating plans in accordance with their terms. If this collection is not conducted or is conducted less frequently, participants and beneficiaries will not have the information necessary to fully exercise their rights and plan fiduciaries will not be able to responsibly operate their plans.

7. SPECIAL CIRCUMSTANCES REQUIRING DATA COLLECTION TO BE INCONSISTENT WITH GUIDELINES IN 5 CFR 1320.5(d)(2)

The DOL claims procedure 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

² For non-grandfathered health plans and issuers offering group insurance coverage, the final regulations shortened the time period from 72 to 24 hours.

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.

8. CONSULTATION WITH INDIVIDUALS OUTSIDE OF THE AGENCY ON AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, CLARITY OF INSTRUCTIONS AND FORMS, AND DATA ELEMENTS

The Departments will be requesting approval of the emergency review requests by the effective date of the interim final rules.

The Departments will be seeking approval for the ICR for 180 days, the maximum allowed for an ICR approved using an emergency review. As part of the emergency review request, the Departments will be requesting that OMB waive the notice requirement set forth in 5 CFR 1320.13(d). Once the emergency submission is approved, the Departments will initiate an ICR Revision, the process required under the PRA to seek up to three (3) years of approval for the information collections. As part of the process, the Departments will open a 60-day and 30-day comment period on the ICR.

9. EXPLANATION OF DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS

No payment or gift has been provided to any respondents.

10. ASSURANCE OF CONFIDENTIALITY OF RESPONSES

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. JUSTIFICATION OF SENSITIVE QUESTIONS

A plan provides information directly to the claimant. Sensitive issues, such as health information, would relate to the claim for which payment is sought, and the initial filing would have been initiated by the claimant or with the claimant's authorization.

12. ESTIMATED BURDEN OF INFORMATION COLLECTION

Note: To give a fair overview of the burden imposed by this ICR shows the estimated annual burden of this ICR while performing the calculations. As the ICR is being submitted as an emergency with a requested approval for 180 day the costs for the first 180 days is reported in the summary sections and in parentheses in the table at the end of this question.

Because ERISA-covered plans already are required to comply with the Agency claims procedure regulation (OMB Control number 1545-2282), the Department did not attribute any cost for these plans to comply with this information collection. As stated above, paragraph (b)(2)(ii) provides additional standards non-grandfathered ERISA-covered plans must meet. The requirement to provide claimants, free of charge, any new or additional evidence considered relied upon, or generated by the plan or issuer in connection with the claim,³ and the requirement to comply either with a State external review process or a Federal review process increases the hour and cost burden imposed on plans and issuers to prepare and deliver the additional information to the claimant.

The burden associated with the additional standards that non-grandfathered and grandfathered ERISA-covered plans must meet is shared equally between the Department of Labor and the Department of the Treasury. The burden discussion below encompasses the combined burden of both agencies. A summary at the end describes the share of the burden allocated to the IRS.

Ongoing burdens are a function of the number of external appeals filed as well as those requiring a fair and full review, which are in turn a function of health claims volume, as well as the denial and appeal rates.

³ Such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date. Additionally, before the plan or issuer can issue an adverse benefit determination on review based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale. The rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.

Claims and Appeals

In Table 1, the total number of claims account for a two percent increase in the out-of-network claims, due to claims related to surprise billing.

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 this information collection associated with any particular type of health benefit claim transaction will range from five minutes for a medical secretary to produce a notice for a fair and full review to as many as 20 minutes for a doctor to draft a response to an appeal brought before an external, independent review organization.

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

	2022 2023		2024	
	Private Sector ESI	Private Sector ESI	Private Sector ESI	
Total Enrollees	136,200	136,200	136,200	
Non-Grandfathered Enrollees	118,494	118,494	118,494	
Total Claims	1,232,812	1,232,812	1,232,812	
Pre-Service				
Claim Approved	31,437	31,437	31,437	
Claim Denied	5,548	5,548	5,548	
Post-Service				
Claim Approved	944,703.5	944,703.5	944,703.5	
Claim Denied	179,374	179,374	179,374	
Claim Extended	71,750	71,750	71,750	
Total Internal Appeals	423.0	423.0	423.0	
Appeals Upheld	169.2	169.2	169.2	

Appeals Denied	253.8	253.8	253.8
Medical subtotal	122.3	122.3	122.3
Appeals Upheld	48.9	48.9	48.9
Appeals Denied	73.4	73.4	73.4
Administrative subtotal	300.8	300.8	300.8
Appeals Upheld	120.3	120.3	120.3
Appeals Denied	180.5	180.5	180.5
Total New External Appeals	12.0	12.0	12.0

The Agency estimates that approximately 93 percent of large benefit and all small benefit plans administer claims using a third-party provider, impacting approximately 95 percent of covered individuals. Therefore, approximately 5.5 percent of covered individuals will have their claims processed in-house. In-house administration burdens are accounted for as hours and discussed in question 12, while purchased services and materials costs are accounted for as dollar costs and discussed in question 13. The hourly burden for plans processing claims in-house is described below:

TABLE 2. —Hour Burden for Claims and Appeals (in thousands)

	Annual
Fair and Full Review	1.2
Notice of Decision External Review	0.2
Total	1.4

Note: Assumed that 7 percent of large plan process these claims in-house in the Group Market. Large plans account for 78.35 percent of policy-holders and therefore 5.5 percent of claims are processed in-house.

The burden hours for claims and appeals are estimated at 1,394 hours annually at an equivalent cost of \$97,616.

Federal External Review

The disclosure requirements of the Federal external review process require (1) a preliminary review by plans of requests for external appeals; (2) Independent Review Organizations (IROs) to notify claimants of eligibility and acceptance for external review; (3) the plan or issuer to provide IROs with documentation and other information considered in making the adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) the plan to notify the claimant and IRO if it reverses its decision; (6) the IRO to notify the claimant and plan of the result of the final external appeal (burden previously accounted for); (7) the IRO to maintain records for six years.

The Departments estimate that there are approximately 84.4 million participants in self-insured ERISA-covered plans. In the States which currently have no external review laws or whose laws do not meet the federal minimum requirements⁴ the Department estimates that there are approximately 8.1 million participants in ERISA-covered plans. These estimates lead to a total of 92.5 million participants. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are an estimated 1.3 external appeals for every 10,000 participants⁵ and that there will be approximately 12,275 external appeals annually. Experience from North Carolina indicates that about 75 percent of requests for external appeals are actually eligible to proceed to an external review, therefore it is expected that there will be about 16,261(12,275/0.75) requests for appeals.

The hour burden related to the preliminary review by plans of the request for external review is estimated to be 4,065 hours (16,261 * 0.25 hours) with an equivalent cost of \$373,303 (4,065 hours * \$91.83). The Department assumes that plans have a human resource specialist with a labor rate of \$91.83.⁶ The human resource specialist will spend an average of 15 minutes for each of the requests, for a plan to make an eligibility determination. Plans will already have conducted internal reviews for eligible claimants; therefore, the required information for plans to make this determination should be readily available.

Once an eligibility determination is made, plans must provide the IRO with all documentation and other information considered in making an adverse benefit determination. The Agency assumes that plans have clerical staff with a labor rate of \$55.23. The clerical staff will spend an average of 5 minutes for each of the requests, for a plan to send documentation to the IRO. As

⁴ These states are Alabama, Florida, Georgia, Pennsylvania, and Wisconsin. See Affordable Care Act: Working with States to Protect Consumers, available at https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html

⁵ AHIP Center for Policy and Research, "An Update on State External Review Programs, 2006," July 2008.

⁶ DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2020 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the 2020 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2017 Service Annual Survey. To estimate overhead cost on an occupational basis, OPR allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2020 dollars.

shown in Table 55, for the 12,275 verified requests for external review, the hour burden for grandfathered and non-grandfathered plans is estimated as 1,023 hours (12,275 * 5 minutes), with an equivalent cost of \$56,494 (1,023 * \$55.23).

This leads to an hour burden of 5,088 hours with an equivalent cost of \$429,797 related to external reviews. During the first six months, the hour burden is estimated to be 2,544 hours with an equivalent cost of \$214,898.

Summary

In total, the annual burden associated with claims, appeals, and external review is approximately 6,482 hours at an equivalent cost of \$527,413 annually. During the first six months for the emergency clearance, the hour burden is estimated to be 3,241 hours with an equivalent cost of \$263,706.

Because the burden is shared equally between the Department of Labor and the Department of the Treasury/IRS, the IRS's annual share is 3,241 hours at an equivalent cost of \$263,706 annually. During the first six months for the emergency clearance, the hour burden for the IRS is estimated to be 1,621 hours with an equivalent cost of \$131,853.

Estimated Annualized Respondent Cost and Hour Burden

Note: The six month burden and number of responses has been included below in parenthesis.

Activity	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden (Hours)	Total Burden (Hours)	Hourly Wage Rate	Total Burden Cost
	7,282	1	7,282	5/60	607	\$55.23	\$33,512
Full and Fair Review	7,202	1	(3,641)	3/00	(304)	\$33.23	(\$16,756)
Notice of Decision	302	1	302	18/60	89	¢160.40	\$15,296
External Review	302	1	(151)	10/00	(45)	\$169.40	(\$7,648)
Preliminary Review by	8,130	1	8,130	15/60	2,033	¢01.02	\$186,652
Plan of Request for External Appeal	0,130	1	(4,065)	15/60	(1,017)	\$91.83	(\$93,326)
Plan Provides IRO with Documentation and other information considered in making adverse benefit determination	6,137	1	6,137 (3,068)	5/60	511 (256)	\$55.23	\$28,247 (\$14,124)
Total	2,524,241*	0.15126	381,826	0.00849	3,241	-	\$263,706
			(190,913)		(1,621)		(\$131,853)

- * The total number of responses is the total number of ERISA-covered group health plans. DOL calculations are based on statistics from Private Pension Plan Bulletin: Abstract of 2018 Form 5500 Annual Reports, Employee Benefits Security Administration (2020).
- ** The number of responses was calculated in the following manner: 16,261 (Preliminary Review) + 12,275 (Notice of Eligibility) + 12,275 (Plan provides IRO with documentation and other information considered in making adverse benefit determination) + 6,137 (IRO send documentation regarding adverse benefit determination to Plan) + 12,275 (IRO sends notice to plan regarding final results of the review) + 12,275 (Record Retention) + 296,117 (Full and Fair Review) + 12,275 (External Review) +1,939 (Linguistically Appropriate Notices) = 381,826

13. ESTIMATED TOTAL ANNUAL COST BURDEN TO RESPONDENTS

Claims and Appeals

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 of either clerical workers (\$55.23)⁷ or doctors (\$169.40)⁸, and then adding the materials and postage costs of mailing responses (\$0.60 each for those not sent electronically).⁹ These costs are described below:

	Service Provider Labor Cost	Service Provider Mailing Cost	In-House Mailing Cost	Total Costs
Fair and Full Review	\$1,080.9	\$94.2	\$4.9	\$1,180.0
Notice of Decision External Review	\$591.5	\$7.6	\$0.4	\$599.4
Total Costs	\$1,672.4	\$101.7	\$5.3	\$1,779.4

The total estimated cost burden for those plans that use service providers, including the cost of mailing all responses (including mailing costs for those responses prepared in-house), is \$1.8 million annually.

^{***} Please note that the numbers in the table are rounded.

⁷ DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2020 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the 2020 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2017 Service Annual Survey. To estimate overhead cost on an occupational basis, OPR allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2020 dollars.

^{9 \$0.55} for USPS First Class Postage and \$0.05 per page of materials costs for two pages of paper.

Non-English Language Assistance

As a result of the May 2011 amendment to the interim final regulations, 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 Agency understands that oral translation services are already provided for nearly all covered participants and beneficiaries. Therefore, no additional burden is associated with this requirement of the amendment.

The Departments/Agency 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), ¹⁰ the Departments estimate that there are about 19.3 million individuals living in covered counties that are literate in a non-English Language. The ACS does not have insurance coverage information. Therefore, to estimate the percentage of the 9.3 million affected individuals that were insured, the Departments used the percent of the population in the state that reported being insured by private employer insurance from the 2016 CPS. ¹¹ This results in an estimate of approximately 3.6 million individuals who are eligible to request translation services.

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

Using the ACS and the CPS, the Departments estimate that there are 19.8 million individuals insured through private employer sponsored insurance living in the affected counties. Based on the foregoing, the Departments estimate that the cost to provide translation services will be approximately \$969,543 annually (19,786,588 lives * 0.098/1000 * \$500).

Federal External Review

The cost burden related to the preliminary review by grandfathered and non-grandfathered ERISA plans of the request for external review is \$9,756. Plans will incur material costs of \$0.05

¹⁰ Data are from the 2013-2017 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. 11 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.

for paper and printing and \$0.55 for postage for each request for external review, resulting in a cost of \$9,756 (16,261 * \$0.60).

Once an eligibility determination is made, plans must provide the IRO with all documentation and other information considered in making an adverse benefit determination. Plans will incur material costs of \$0.05 for each sheet of paper. The Departments assume that each set of documentation will be 20 pages. Plans will also incur a cost of 0.55 for postage for each set of documentation, resulting in a cost burden of 19,026 ($12,275 \times 0.05 \times 20 + 12,275 \times 0.55$). The Departments estimate that this will cost, on average, 1.55 per claimant.

IROs must also send each eligible claimant a notice of eligibility and acceptance. The Departments assume that the IRO has clerical staff with a labor rate of \$55.23 that will spend, on average five minutes per claimant preparing the notice, and that IROs incur an average cost of \$0.60 to print and mail the notice. For the 12,275 verified requests for external review, the cost burden for the clerical worker to send the notice of eligibility and acceptance is estimated to be \$56,493 (12,275 x 5 minutes x \$55.23). Additionally, IROs will incur material costs of \$0.05 for each sheet of paper. The Departments assume that each notice of eligibility and acceptance will be 1 page. Plans will also incur a cost of 0.55 for postage for each set of documentation, resulting in a cost of 0.255 (12,275 x 0.05 + 12,275 * 0.55). Thus, the total cost burden relating to the notice of eligibility and acceptance is 0.55

IROs are required to send to plans all documents that claimants submit. The Departments do not know what fraction of claimants will submit additional documentation, but for purposes of this burden analysis assume that half of claimants (6,137) do. The Departments assume that the IRO has clerical staff with a labor rate of \$55.23 that will spend, on average five minutes per claimant preparing and forwarding the required documents, and that IROs incur an average cost of \$1.05 to print and mail the documents. For the 6,137 verified requests for external review, the cost burden for the clerical worker to send the claimants' documentation to the plans is estimated to be \$28,247 $(6,137 \times 5 \text{ minutes } \times \$55.23)$. Additionally, IROs will incur material costs of \$0.05 for each sheet of paper. The Departments assume that such documentation will be 10 pages. Plans will also incur a cost of \$0.55 for postage for each set of documentation, resulting in a cost of $\$6,444 (6,137 \times \$0.05 \times 10 + 12,275 * \$0.55)$. Thus, the total cost burden relating to preparing and forwarding the required documents is \$34,691.

IROs are required to notify the claimant and plan of the result of the final external appeal. The Departments estimate that preparing and sending the notices for each of the 12,275 external reviews will take IRO clerical staff, with a labor rate of \$55.23, on average five minutes per claimant and that IROs incur an average cost of \$1.05 to mail the documents. For the 12,275 verified requests for external review, the cost burden for the clerical worker to send the notice is estimated to be \$56,494 (12,275 x 5 minutes x \$55.23). Additionally, IROs will incur material costs of \$0.05 for each sheet of paper. The Departments assume that such documentation will be 10 pages. Plans will also incur a cost of 0.55 for postage for each set of documentation, resulting in a cost of 12,888 (12,275 x 0.05 x 10 + 12,275 * 0.55). Thus, the total cost burden relating to notifying the claimant and plan of the final external appeal result is 0.55

IROs also are required to maintain records of all claims and notices associated with the external review process for six years. The Departments believe that these documents would be retained as a customary part of business, but estimate that clerical staff will spend on average an additional 5 minutes per claimant ensuring all files are complete. For the 12,275 verified requests for external review, the cost burden for the clerical worker to maintain records is estimated to be \$56,494 (12,275 x 5 minutes x \$55.23).

The Department/Agency is not able to estimate the number of reversals and the associated notices to claimants and IROs that plans would send due to reversing its prior decision, but believes the number would be small.

The Departments estimate that the federal external review procedures will result in a cost burden of \$253,207 annually. During the first six months, the cost burden is estimated to be \$126,603.

Summary

In total, the cost burden associated with claims, appeals, language translation, and external review is approximately \$3,255,357 annually. During the first six months, the cost burden is estimated to be \$1,627,679.

Because the burden is shared equally between the Department of Labor and the Department of the Treasury/IRS, the IRS's share approximately \$1,627,679 annually. During the first six months, the cost burden for DOL is estimated to be \$813,839.

14. ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT

There is no annualized cost to the federal government.

15. REASONS FOR CHANGE IN BURDEN

The No Surprises Act extends the balance billing protection related to external reviews to grandfathered plans. Under Section 110 of the No Surprises Act, grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections.

Adjustments to the burden estimates result from updated estimates on the number of ERISA-covered plans and policyholders and increases in wage rates and postage rates. These updated data inputs decrease the hour burden by -650 hours compared with the prior submission and decrease the cost burden by \$329,397 compared with the prior submission.

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	190,913	-87,499	0	0	0	278,412
Annual Time Burden (Hr)	1,621	-650	0	0	0	2,271
Annual Cost Burden (\$)	813,839	-329,397	0	0	0	1,143,236

16. PLANS FOR TABULATION, STATISTICAL ANALYSIS AND PUBLICATION

There are no plans for tabulation, statistical analysis, and publication.

17. REASONS WHY DISPLAYING THE OMB EXPIRATION DATE IS INAPPROPRIATE

The IRS believes that displaying the OMB expiration date is inappropriate because it could cause confusion by leading taxpayers to believe that the regulations sunset as of the expiration date. Taxpayers are not likely to be aware that the Service intends to request renewal of the OMB approval and obtain a new expiration date before the old one expires.

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

Note: The following paragraph applies to all of the collections of information in this submission:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.