Supporting Statement Part A

-

Affordable Care Act Internal Claims and Appeals and External Review Procedures for Nongrandfathered and Grandfathered Group Health Plans and Issuers and Individual Market Issuers for Paperwork Reduction Act Submission

(CMS-10338/OMB Control Number 0938-1099)

A. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, (the Affordable Care Act) was enacted by President Obama on March 23, 2010. As part of the Act, Congress added PHS Act section 2719, which provides rules relating to internal claims and appeals and external review processes. On July 23, 2010, an interim final rule (2010 IFR) was published implementing section 2719 of the PHS Act. On June 24, 2011, the 2010 IFR was amended specifying rules governing the internal claims and appeals and external review processes. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) finalized the 2010 IFR on November 18, 2015 (2015 final rule). The 2015 final rule clarifies consumer rights and aligns the appeals process across all types of plans, starting in 2018. The 2015 final rule will be herein after referred to as the "Appeals regulation".

The Consolidated Appropriations Act (CAA) of 2021, which includes Section 110 of the No Surprises Act, https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdfadds new sections 2799A-1 and 2799A-2 to the PHS Act, which protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from receiving surprise medical bills when they receive emergency services, non-emergency services from non-participating providers at participating facilities, and air ambulance services, under certain circumstances. The CAA also amends section 2719 of the PHS Act to require the external review process to apply with respect to any adverse determination by a plan or issuer involving items and services subject to the surprise billing and cost-sharing protections under section 2799A-1 or 2799A-2 of the PHS Act. Interim final rules titled "Requirements Related to Surprise Billing; Part II" (September 2021 IFR) were published, implementing certain provisions of the CAA, including the provision regarding the requirement that the external review process apply to items and services subject to determinations involving 2799A-1 or 2799A-2 of the PHS Act. The No Surprises Act extends these protections to grandfathered plans and the Departments implemented section 110 of the No Surprises Act to make external review available to individuals enrolled in grandfathered health plans or coverage

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA), the Centers for Medicare & Medicaid Services (CMS) has submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting emergency review and approval to begin collecting information that is essential to implementing surprise billing requirements under the No Surprises Act. The

surprise billing requirements for grandfathered plans as described under the September 2021 IFR apply for plan years beginning on or after January 1, 2022. The use of the normal PRA procedures is likely to prevent HHS from collecting information, such as data related to external review determinations for grandfathered plans, that will be essential to meeting the effective dates of the No Surprises Act. In accordance with 5 CFR 1320.13(a)(2)(i), we believe that public harm will result if the standard, non-emergency clearance procedures are followed.

B. Justification

1. Need and Legal Basis

With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the Appeals regulation 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 of the Department of Labor (DOL) claims procedure regulation, and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulation. Paragraph (b)(3)(i) requires issuers offering coverage in the individual health insurance market to also comply with the DOL claims procedure regulation as updated by the Secretary of Health and Human Services (HHS) in paragraph (b)(3)(ii) of the Appeals regulation for their internal claims and appeals processes.

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

1 Such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.

Additionally, before the plan or issuer can issue an adverse benefit determination on review based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale. The rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit

PHS Act section 2719 further requires that non- grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual coverage comply with either a state external review process in which the issuer operates or a federal external review process. The Appeals regulation provides 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.

Starting in 2018, all plans and issuers are required to comply with the federal consumer protection standards for the appeals process. To the extent the state in which the issuer operates does not meet the minimum federal external review standards, or the plan or issuer is not subject to a state external review process, the plan or issuer may choose to either contract with an Independent Review Organization (IRO) (also referred to as a Private, Accredited IRO), as described in section 45 CFR 147.136(d)(2) of the Appeals regulation, or participate in the HHS-administered federal external review process described in section 45 CFR 147.136(d)(4) of the Appeals regulation.

If claimants belong to plans that elect to participate in the HHS-administered federal external review process, those claimants may submit a request via a web-based portal, mail, email, or fax directly to HHS.[2] The web- based portal may be used to request an external review of a plan's or issuer's determination and to check on the status of their submitted request. Claimants who request a review online are required to attach pertinent and relevant documentation which provides support for their request for an external review. The DOL 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. The Appeals regulation includes additional requirements for employee benefit plans that must be met or exceeded, as described in DOL Technical Guidance 2011-02.[3]

The CAA of 2021 amended section 2719 of the PHS Act to require the external review process to apply with respect to any adverse determination by a plan or issuer involving items and services subject to the surprise billing and cost-sharing protections under section 2799A-1 or 2799A-2 of the PHS Act. In order to implement this expansion, the Appeals regulations at 45 CFR 147.136 were amended by the September 2021 IFR. In particular, the September 2021 IFR amends the 2015 final rules to broaden the scope of external review requirements and explicitly require, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A1

2 Standards for Self-Insured Non-Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage Using the HHS Administered Federal External Review Process; https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/FERP-Guidance-8-29-2018.pdf

3 Guidance on External Review for Group Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage, and Guidance for States on State External Review Processes; https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/technical-releases/11-02

or 2799A-2 is eligible for external review. Additionally, the September 2021 IFR extends the external review requirement to grandfathered health plans and coverage for adverse benefit determinations involving items and services covered by requirements of PHS Act section 2799A-1 or 2799A-2.

The disclosure requirements of the federal external review process include (1) preliminary review by plans of requests for external reviews; (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 adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) plans 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 review; and (7) the IRO to maintain records for six years.

2. Information Users

The information collection requirements included in the DOL claims procedure regulation and the Appeals regulation ensure that claimants receive adequate information regarding the plan's claims procedures and the plan's handling of specific benefit claims. Claimants need to understand plan procedures and plan decisions in order to appropriately request benefits and/or appeal benefit denials. The information collected in connection with the HHS-administered federal external review process is collected by HHS, and is used to provide claimants with an independent external review.

3. Use of Information Technology

The DOL claims regulation and the Appeals regulation do not restrict plans' use of electronic technology to process and pay claims, to maintain information on the basis for claim determination, and to generate correspondence related to claims processing decisions.

The Appeals regulation provides consumers a secure, online portal, which may be used as an additional tool to request and process HHS-administered federal external review requests.

4. Duplication of Efforts

There is no duplication of efforts for these information collection requirements. In some circumstances, states may require substantially similar information to be provided to insured persons and any such information disclosure may be used to satisfy any potential duplicative or overlapping requirements.

5. Small Businesses

The regulation applies to all employee benefit plans and therefore is likely to affect small entities that provide health care benefits. For the purposes of the 2015 final rule, small entities that fall under HHS' regulatory authority includes small health insurance insurers and small self-insured nonfederal governmental health plans.

We believe that few, if any, insurance companies underwriting comprehensive health insurance policies are small entities. Using data from the 2009 Current Population Survey, HHS estimates that the Appeals regulation will affect an estimated 5.73 percent of nonfederal governmental health plans that qualify as small plans. HHS considered 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 HHS has taken this fact into account in deriving its burden estimates. These service providers typically develop a single claims processing system to service a large number of customers, including small entities. The cost of revising and implementing the procedures is therefore spread widely over a large number of small plans, minimizing burden on those plans. Moreover, small plans and their respective enrollees benefit equally from the service provider's expertise and ability to provide improved accuracy and timeliness in claims and appeals determinations.

6. Less Frequent Collection

The information collection requirements arise in connection with the occurrence of individual claims for benefits, and consist of third-party notices and disclosures. No information is reported to the federal government other than that which is necessary for HHS to facilitate an external review. The information collection provisions of the regulation ensure that sufficient information is provided to claimants so that they may fully exercise their rights under their coverage. The information collection is necessary to ensure that claimants in plans or policies in states whose external review processes do not meet the requirements of 2719(b)(1) and 2719(b)(2), as well as plans not subject to their state's external review process can access their rights as described in PHS Act Section 2719.

7. Timing of Notification

The DOL claims procedure regulation, the Appeals regulation and federal external review process guidelines together impose special timing requirements for the handling of claims in the fully insured and small group markets, self-funded nonfederal governmental health plans, and plans not subject to a state external review process in cases where the state does not have an external review process that meets federal requirements. 45 CFR 147.136(b)(2) of the Appeals regulation also provides a basis for special timing requirements set forth by the DOL claims procedure regulation.

First, for health care claims involving “urgent care”, 45 CFR 147.136(b)(2)(ii)(B) of the Appeals regulation provides processes set forth by the DOL claims procedure regulation, which requires, in general, that claimants be notified of health benefit determinations “as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim.” 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..

Second, for “pre-service” health care claims, 45 CFR 147.136(b)(22) of the Appeals regulation, incorporates the requirement from the DOL claims procedure regulation 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.”. Pre-service claims involve 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 care benefit claims, 45 CFR 147.136(b)(22) of the Appeals regulation incorporates the requirement from the DOL claims procedure regulation that notification of an adverse benefit determination be given “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.

To facilitate external review for claimants in plans or coverage not subject to a state external review process, the plans or issuers are required to electronically notify HHS as to whether they are subject to a federal external review process under PHS Act 2719 and to specify the insurance plan (s) to which it applies. If the plans is subject to a federal external review process under PHS Act Section 2719, the plan or issuer is required to notify HHS which federal external review process they are using and provide contact information for designated personnel in their appeals department, including names, mailing address, telephone numbers, facsimile numbers and e-mail addresses. Issuers and self-funded nonfederal governmental health plans that elect to use the HHS-administered federal external review process will also be required to provide the claimants’ relevant files to the HHS external review contractor in fewer than five days, upon request.

These timing requirements are related to policy objectives in an area of important public concern. For example, the shortest time frame for “urgent care” claims apply only under circumstances in which delay could seriously jeopardize the life or health of the claimant, the ability of the claimant to regain maximum function, or where delay would subject the claimant to severe pain. The next shortest time frame applies under pre-service claims 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 or coverage requires preapproval of the medical care before providing such products or services. Post-service health claims and disability claims also involve important concerns relating to the sick and

disabled, but under these circumstances, plans may take up to 4545 days to respond if it is reasonably necessary to do so. The time frames also service to ensure that claimants are given a response to their appeal and can escalate to another level of appeal, if needed, within a reasonable amount of time.

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

8. Federal Register/Outside Consultation

An interim final rules titled "Requirements Related to Surprise Billing; Part II" published October 7, 2021. The public solicitation for comments related to these information collection requirements will be open for a period of 60 days.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these data collections.

10. Confidentiality

To the extent of applicable law and HHS policies, HHS will maintain consumer privacy with respect to the information disclosed.

11. Sensitive Questions

These data collections involve no sensitive questions.

12. Burden Estimates (Hours & Wages)

12.1 Internal Claims and Internal Appeals Process (45 CF 147.136)

HHS estimates that this information collection will affect an average 109,653 respondents per year, over the next three years. HHS expects the number of respondents will increase over time as more plans relinquish grandfathered status and must comply with the regulations. The frequency of response will be on occasion, mirroring the frequency of benefit claims that require responses, resulting in an estimated average hourly burden of 1,195,529 hours and with an associated average cost of $184 million per year over the next three years. It is expected that there will be an increase in the hour burden and associated cost as grandfathered plans continue to lose that status in future years. Although grandfathered plans are not subject to the current regulations, the September 2021 IFR extends the balance billing protections related to external reviews to grandfathered plans.

Under PHS Act section 2719, all sponsors of non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must comply with all requirements of the DOL claims regulation as well as the new standards that are established by the Secretary of Labor and the Secretary of Health and Human Services in paragraphs (b)(2) and (b)(3) of the 2015 FR. These estimates include only ongoing costs of compliance with the statute, the DOL claims regulation, and the Appeals regulation. Average labor costs are calculated using data from the Bureau of Labor Statistics[4].

TABLE 1: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/ hour)	Adjusted Hourly Wage ($/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43-6014	$28.96	$55.23
Physician (all other)	29-12281228	$154.74	$169.40
Lawyer	23-1011	$105.28	$140.96
Human Resources Manager	13-1070	49.09	$91.83
Medical Secretaries	43-6013	$18.13	$46.07

Ongoing burdens are a function of claims volume, as well as the denial and appeal rates of all plans. Each covered individual was estimated to generate 10.2 claims on average per year[5], 82 percent of which were filed electronically. The Departments then assumed that 15 percent of these claims were denied.[6] The Departments assumes that three percent of these claims were pre-service with the remaining being post-service claims. The

4 May 2020 Occupational Employment Statistics found at https://www.bls.gov/oes/2020/may/oes_stru.htm#430000. Adjusted hourly wages are calculated as follows: (2020 BLS mean wage rate)/(ECEC ratio)*(Overhead load factor)*(inflation rate)^2(inflated 2 years from base year).

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

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

number of post-service claims extended was based on the share of ‘‘clean’’ claims that took more than 30 days to complete processing. The share of denials expected to be appealed, 0.2 percent, was based on a RAND study.[7] The Departments expects half of these appeals to be reversed, and those not reversed were divided between ‘‘medical claims’’ (28.9 percent) and ‘‘administrative claims’’ (71.1 percent).

The transaction burden will vary widely with the type and complexity of the claim in question, but the mix of claims and associated burdens generally are expected to be similar across plans of the same type. The average time required for the information collection associated with any particular type of health benefit claim transaction will range from one minute for certain routine automatic notices to four and a half hours for certain disclosures on requests related to adverse benefit determinations. The Departments attributed costs to notifying individuals of denied claims and processing appeals. Initial denials were assumed to only take a few minutes for a clerical worker to draft and send an adverse benefit determination notice based on the model notice issued by the Departments that does not require any information to be included that cannot be auto-populated.

Appealed denials deemed “medical” in nature will require a physician 4.5 hours (at a rate of $169.40) to review relevant appeals materials, make a determination, and draft a one page response, resulting in an estimated cost of $762.30 per “medical” denial. Appealed denials deemed “administrative” in nature will require a legal professional (at a rate of $140.96) approximately 2 hours to review the relevant materials and make a decision related to a reversal or approval of a denial and draft a two page response, resulting in an estimated cost of $ 281.92. Each notice of adverse benefit determination and notice of the decision of an internal appeal will incur a mailing cost estimated at $0.65 per notice including, printing ($0.05 per page), and postage costs ($0.55 postage).

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

TABLE 2.--Hour and Cost Burden (in thousands)

	Claims Government Sector ESI	Claims Individual Market	In-House Burden Hours	In-House Burden Hours Equivalent	In-House Burden Mailing	Out-House Burden Mailing	OutHouse Burden Labor Costs	In and Out House Cost Burden

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

				Costs	Costs	Cost		Total Cost Burden
Pre-Service Claim Approved	9,635	3,530	58.8	$3,065	$413.0	$1,066	$7,906	$4,895.9
Pre-Service Claim Denied	1,700	623	20.8	$1,082	$72.9	$188	$2,791	$1,537.3
Post-Service Claim Denied	54,977	20,144	671.5	$34,976	$2,356.8	$6,080	$90,226	$49,707.5
Post-Service Claim Extended	13,634	6,422	107.0	$5,575	$751.4	$1,508	$11,188	$7,013.9
Denial Appeal Total	77.8	36.6	186.8	$21,870	$23.8	$80	$43,887	$51,714.0
Appeal Upheld	51.9	24.4	47.9	$7,776.2	$17.7	$31.9	$13,978	$14,0276
Appeal Denied	77.8	36.6	160.6	$24,414.9	$26.6	$41.8	$43,887	$43,955.4
Medical Sub-Total	37.5	17.6	149.7	$24,352.0	$12.8	--	$43,774	$43,786.8
	Claims Government Sector ESI	Claims Individual Market	In-House Burden Hours	In-House Burden Hours Equivalent Costs	In-House Burden Mailing Costs	Out-House Burden Mailing Cost	OutHouse Burden Labor Costs	In and Out House Cost Burden Total Cost Burden
Claim Upheld	15.0	7.1	47.3	$7,690.1	$5.1	--	$13,823	$13,828.1
Claim Denied	22.5	10.6	102.5	$16,661.9	$7.7	--	$29,951	$29,958.7
Admin Sub Total	92.2	43.4	58.8	$7,839.2	$31.5	--	$14,091	$14,122.5
Claim Upheld	36.9	17.4	0.6	$86.1	$12.6	--	$155	$167.6

Claim Denied	55.3	26.1	58.2	$7,753.0	$18.9	--	$13,936	$13,954.9
Fair and Full Review	90.8	42.8	4.0	$207.2	$16.6	$29.9	$304.2	$323.7
Notice of Decision External Review	2.2	0.2	0.1	$15.9	$0.2	$1.4	$103.0	$104.6
Total	80,415	30,939	1,671	$163,157	$3,751	$8,997	$329,696	$415,023

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

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

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

12.2 Non-English Language Assistance (45 CFR 147.136)

As a result of the Appeals final regulation, plans and issuers must provide claimants 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.

HHS 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),[6] the HHS estimates that there are about 9.3 million individuals living in covered counties that are literate only in a non-English Language. The ACS does not have insurance coverage information. Therefore, to estimate the percentage of the 8.7 million affected individuals who were insured, HHS used the percent of the population in the state that reported being insured by nonfederal government employer insurance from the 2014 CPS.[7] This results in an estimate of approximately 2.1 million individuals who are eligible to request translation services.

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

Using the ACS and the CPS, HHS estimates that there are 11.6 million individuals insured through nonfederal governmental employer sponsored insurance or through the individual insurance market living in the affected counties. Based on the foregoing, HHS estimates that the cost to provide translation services will be approximately $567,251 annually (11,576,541 lives * 0.098/1000 * $500).

12.3 Existing External Review Requirements for Non-Grandfathered Plans (45 CFR 147.136)

This ICR also accounts for the existing burden of the disclosure requirements of the federal external review process for health insurance issuers in states where state external review processes do not meet the (b)(1) or (b)(2) standard of PHS Act 2719 [see "Guidance on External Review for Group Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage and Guidance for States on State External Review Processes" on the CCIIO website at http://cciio.cms.gov], and self-funded nonfederal governmental plans not subject to a compliant state or territory external review process [see "Instructions for Self Insured Non- Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage on How to Elect a federal external review process" on the CCIIO website at http://cciio.cms.gov]. Note that both health insurance issuers and self-funded nonfederal governmental health plans have an option of contracting with Independent Review Organizations (IROs) as described in the HHS Technical Release 2017-02 [8]. Both health insurance issuers in states that are non-compliant with federal external review process standards, and plans not subject to a state external review process must disclose electronically to HHS whether they will use the HHS-administered federal external review process or are following the process outlined in HHS Technical Release 2011-02. This burden is accounted for in this ICR.

Health insurance issuers in states that do not have a compliant external review process and plans not subject to a state external review process that have opted to use the HHS administered federal external review process or the Department of Labor's federal external review process ("applicable plans and issuers") will be required to notify HHS as to which

8 Guidance on Standards for Self-Insured Non-Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage Using the HHS-Administered Federal External Review, available at: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/FERP-Guidance_Final4_01-1117-MM-508.pdf.

federal external review process they will be using via the Health Insurance Oversight System (HIOS). If they are using the HHS- administered federal external review process, they will also be required to electronically submit to HHS all notices pertaining to external review rights including the notice of adverse benefit determinations and the notice of final internal adverse benefit determinations. If these notices are updated at any time, updated copies of these notices will need to be submitted to HHS.

The HHS-administered federal external review process also requires that; 1) the CMS appointed examiner ("the examiner") must conduct a preliminary review of a claimant's eligibility for external review; 2) applicable plans and issuers must provide the examiner with documentation and other information considered in making adverse benefit determinations or final adverse benefit determinations; 3) the examiner must notify the claimants who are ineligible for external review that they are ineligible; 4) the examiner must forward to the applicable plan or issuer any information submitted by the claimant; that if the applicable plan or issuer reverses its decision, it must notify the claimant and
the examiner; 6) the examiner must notify claimant and the applicable plan or issuer of result of final external review (burden previously accounted for); and 7) the examiner must maintain records for six years.

Health insurance issuers and self-funded nonfederal governmental plans in states where the state external review processes do not meet the (b)(1) or (b)(2) standard of PHS Act 2719 that decide to follow the external review process will be subject to the following different set of requirements as described in section 45 CFR 147.136(d)(2) of the Appeals regulation,: 1) Issuers must conduct a preliminary review of claimant requests for external review in order to determine eligibility; 2) following the preliminary review, issuers must notify the claimant whether or not they are eligible for external review; 3) if the claimant is eligible, the issuer must forward to the IRO all documentation and other information considered when making its adverse benefit determination; 4) the IRO must forward all information submitted by the claimant back to the issuer; 5) next, the IRO must notify claimant and the applicable plan or issuer of the result of the final external review; and finally, the IRO must retain its records for six years.

It is estimated that there will be 4,049 external reviews conducted in a year for the affected population.[99] The total hour burden associated with the federal external review process for affected self-funded nonfederal governmental health plans and health insurance issuers is 1,788 with an equivalent cost of $128,876. HHS made reasonable estimates for the amount of time it would take for each of the steps outlined above, assuming that a clerical worker could prepare most of the documents that would need to be sent forward. HHS used salary data provided by the Department of Labor National Occupational Employment Survey.

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

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

Summary

Total burden hours are estimated at 1,195,626 hours annually for 2021, 2022 and 2023. Equivalent costs are estimated at $83,629,389 million annually for 2021, 2022 and 2023.

TABLE 3: HHS' Summary of Existing Burden

Year	Estimated Number of Responses	Total Annual Burden (Hours)	Total Estimated Labor Cost	Total Estimated Cost Burden
2022	516,626,544	1,195,626	$83,629,389	$184,134,300
2023	516,626,544	1,195,626	$83,629,389	$184,134,300
2024	516,626,544	1,195,626	$83,629,389	$184,134,300

12.4 External Review Requirements for Non- Grandfathered Plans and Grandfathered plans (45 CFR 147.136)

The No Surprise Act extends the protections related to external reviews to grandfathered plans. Grandfathered plans must comply either with a state external review process or a federal review process. The disclosure requirements of the federal external review process require (1) a preliminary review by plans of requests for external review; (2) 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 adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) plans 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; 7) the IRO to maintain records for six years.

HHS already has an existing information collection on the claims, appeals, and external review requirements for non-grandfathered plans (OMB control number: 0938-1099). Due to the September 2021 interim final rule, HHS has added the burden associated with the external review requirements for grandfathered plans and non-grandfathered plans in the information collection.

HHS estimates that there are approximately 84.4 million participants in self-insured ERISA-covered plans, grandfathered non-federal governmental plans and in grandfathered individual market coverage. Prior to the interim final rules, HHS estimates that there are approximately 8.1 million participants in plans in the states which have no external review laws or whose laws do not meet the federal minimum requirements.[10] 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.

HHS estimates that there are an estimated 1.3 external reviews for every 10,000 participants[11] and that there will be approximately 12,275 external reviews annually. Experience from North Carolina indicates that about 75% of requests for external reviews are actually eligible to proceed to an external review,[12] therefore it is expected that there will be about 16,261 (12,275/0.7549) requests for external review. In addition, a 2% increase in the number of out-of-networks claims was incorporated in the estimate to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review.

As shown in Table 4, the hour burden related to the preliminary review by grandfathered and non-grandfathered plans of the request for external review is estimated to be 4,065 hours (16,261 *0.25 hours) with an equivalent cost of $383,060 (4,065 hours * $91.83). HHS assumes that plans have a human resources specialist with a labor rate of $91.83. 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. Additionally, plans will incur material costs of $0.05 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).

TABLE 4: Annual Burden and Cost for Plans to Conduct a Preliminary Review of the Request for the External Review Starting in 2022

Year	Estimated Number of Responses	Total Annual Burden (Hours)	Total Estimated Labor Cost	Other Costs	Total Estimated Cost
2022	16,261	4,065	$373,303	$9,756	$383,060

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

11 AHIP Center for Policy and Research, "An Update on State External Review Programs, 2006," July 2008. 12 North Carolina Department of Insurance. "Health Insurance Smart NC: Annual Report on External Review Activity 2013." https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531.

Once an eligibility determination is made, plans must provide the IRO with all documentation and other information considered in making an adverse benefit determination. HHS 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 shown in Table 5, 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). Additionally, plans will incur material costs of $0.05 for each sheet of paper. HHS assumes 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 x $0.05 x 20 + 12,275 * $0.55). HHS estimates that this will cost, on average, $1.55 per claimant**.**

TABLE 5: Annual Burden and Cost for Plans to Provide the IRO with Documentation Starting in 2022

Year	Estimated Number of Responses	Total Annual Burden (Hours)	Total Estimated Labor Cost	Other Costs	Total Estimated Cost
2022	12,275	1,023	$56,494	$19,026	$75,519

IROs must also send each eligible claimant a notice of eligibility and acceptance. HHS assumes that the IRO has clerical staff with a labor rate of $55.23 that will spend, on average 5 minutes per claimant preparing the notice, and that IROs incur an average cost of $0.60 to print and mail the notice. As shown in Table 6, 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 $56,494 (12,275 x 5 minutes x $55.23). Additionally, IROs will incur material costs of $0.05 for each sheet of paper. HHS assumes 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 $7,365 (12,275 x $0.05 + 12,275 * $0.55). Thus, the total cost burden relating to the notice of eligibility and acceptance is $63,858.

TABLE 6: Annual Burden and Cost for IROs to Send Notice of Eligibility and Acceptance Starting in 2022

Year	Estimated Number of Responses	Total Annual Burden (Hours)	Total Estimated Labor Cost	Other Costs	Total Estimated Cost
2022	12,275	1,023	$0	$7,365	$63,858

IROs are required to send to plans all documents that claimants submit. HHS does 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. HHS assumes that the IRO has

clerical staff with a labor rate of $55.23 that will spend, on average 5 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. As shown in Table 7, 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 x 5 minutes x $55.23). Additionally, IROs will incur material costs of $0.05 for each sheet of paper. HHS assumes 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 x $0.05 x 10 + 12,275 * $0.55). Thus, the total cost burden relating to preparing and forwarding the required documents is $34,691.

TABLE 7: Annual Burden and Cost for IROs to Send Plans all Documents that Claimants Submit Starting in 2022

Year	Estimated Number of Responses	Total Annual Burden (Hours)	Total Estimated Labor Cost	Other Costs	Total Estimated Cost
2022	6,137	511	$28,247	$6,444	$34,691

IROs are required to notify the claimant and plan of the result of the final external appeal. HHS estimates 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 5 minutes per claimant and that IROs incur an average cost of $1.05 to mail the documents. As shown in Table 8, 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. HHS assumes 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 $69,382.

TABLE 8: Annual Burden and Cost for IROS to Notify the Claimant and Plan of the Result of the Final External Appeal Starting in 2022

Year	Estimated Number of Responses	Total Annual Burden (Hours)	Total Estimated Labor Cost	Other Costs	Total Estimated Cost
2022	12,275	1,023	$56,494	$12,888	$69,382

IROs also are required to maintain records of all claims and notices associated with the external review process for six years. HHS is of the view 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. As shown in Table 9, 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).

TABLE 9: Annual Burden and Cost for IROS to Maintain Record of All Claims and Notices Starting in 2022

Year	Estimated Number of Responses	Total Annual Burden (Hours)	Total Estimated Labor Cost	Other Costs	Total Estimated Cost
2022	12,275	1,023	$0	$56,494	$56,494

HHS estimates that the federal external review process will result in an hour burden of 5,088 hours with an equivalent cost of $429,797 related to external reviews. The cost burden of approximately $253,207 annually. The cost burden results from the cost associated with preparing and mailing required notices and documents. HHS is not able to estimate the number of reversals and the associated notices to claimants and IROs that plans would send due to reversing prior decisions, but HHS is of the view that the number would be small.

HHS estimates that there are approximately 13.5 million individual market enrollees and 19.3 million non-federal governmental plans enrollees.[12] These estimates lead to a total of 32.8 million total enrollees in individual market and non-federal government plans. Among the 32.8 million participants, 2.6 million are in grandfathered plans and 30.1 million are in non-grandfathered plans. HHS also added a two percent increase in the number of out-of networks claims to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review resulting in an adjusted total of 30.7 million for non-grandfathered plans and an adjusted total of 33.3 million for all individual market and non-federal government plans.

HHS also estimates there are an estimated 1.3 external reviews for every 10,000 participants and that there will be approximately 4,337 total external reviews annually for individual market and non-federal government plans. This amount includes 3,994 reviews for non-grandfathered plans and 343 for grandfathered plans. Experience from North Carolina indicates that about 75% of requests for external reviews are actually eligible to proceed to an external review, therefore it is expected that there will be about 5,783 requests for external

12 Individual market based on data from MLR annual report for the 2019 MLR reporting year, available at https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr. Non-federal government plans data from Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2019 Medical Expenditure Panel Survey-Insurance Component.

review. This amount includes 5,326 requests for non-grandfathered plans and 457 requests for grandfathered plans.

As shown in Table 10, HHS estimates that the disclosure requirements will require 3,066 burden hours that result in $222,224 in estimated labor costs and $19,625 in other costs for printing and mailing. The total estimated updated burden for federal external review to individual market and non-federal government plans is $241,850. This amount includes $222,729 in costs for non-grandfathered plans and $19,121 for grandfathered plans.

TABLE 10: HHS' Summary Table New Collection Burden for Federal External Review

Year	Estimated Number of Responses	Total Annual Burden (Hours)	Total Estimated Labor Cost	Other Costs	Total Estimated Cost
2022	5,783	3,066	$222,224	$19,625	$241,850
2023	5,783	3,066	$222,224	$19,625	$241,850
2024	5,783	3,066	$222,224	$19,625	$241,850
3 Year Average	5,783	3,066	$222,224	$19,625	$241,850

The existing information collection had an estimated hour burden of 1,394 hours with an equivalent cost of $97,616 and an estimated cost burden by $3,002,150.

In summary, the total burden associated with the information collection, including the existing collection, is approximately 6,307 hours at an equivalent cost burden of approximately $3,497,208 annually. Because the burden is shared equally between the DOL and the Department of the Treasury, the DOL's share is 3,241 hours at an equivalent cost of 263,706 annually. The DOL's share of the cost burden is $1,627,679 annually. As HHS, DOL and the Department of the Treasury share jurisdiction, HHS will account for 50 percent of the burden, or 3,066 hours with an equivalent cost of $241,850. The summary of burden for HHS, DOL and the Department of the Treasury's information collection has also been provided below.

13. Capital Costs

13.1 ICRs Regarding Disclosure for Self-Insured Plans Opting-in to State Law (45 CFR 149.30)

As indicated in question 12, the bulk of Group Market claims will be processed by third-party service providers. Total cost is estimated by multiplying the number of responses by the amount of time required to prepare the documents and then multiplying this by the appropriate hourly cost of either clerical workers

($5,555.23).[13] _bookmark9, doctors ($169.40)[14] _bookmark10or lawyers ($140.9696)[16], and then adding the cost of copying and mailing responses ($0.65)[15] each for those not sent electronically) . These costs are described in Table 1. 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 $184.1 million annually.[16] _bookmark13

Federal External Review Process

It is estimated that there will be an annual administrative cost burden of $59,826 on average over the next three years associated with the federal external review process. This administrative cost burden is a result of sending the files and notices required by the proposal to the independent examiner for health insurance issuers and self-funded nonfederal governmental health plans using the federal external review process.

14. Cost to Federal Government

Government program staffing costs, to provide technical assistance to respondents, are based on one 14 Grade/Step 1 in the Washington D.C. area.

GS-14: hourly rate **$**64 at 1.3 hours a week: Annual cost: $ 79,022

15. Changes to Burden

The overall burden has increased from 1,195,626 hours to 1,198,692 hours, resulting in a total burden increase of 3,066 hours. The increase is mainly attributed to grandfathered plans required to meet external review standards for adverse benefit determinations subject to the surprise billing and cost-sharing protections.

13 Secretaries, Except Legal, Medical, and Executive (43-6014): $208208.96(20202020 BLS Wage rate)/0.675(ECEC ratio)*1.2(Overhead Load Factor) *1.023(Inflation rate) ^2(Inflated 2 years from base year) = $5555,23

14 Family and General Practitioner (29-1062): $154.74(202074(2020 BLS Wage rate) /0.69(ECEC ratio) *1.35(Overhead Load Factor) *1.023(Inflation rate) ^2(Inflated 2 years from base year) = $169.4040 [16] The Department's estimated 20202020 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from 2020 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics.

15 Cost of copying and mailing responses (0.54 each for those not sent electronically). $0.55 for USPS First Class Postage and $0.05 per page of materials costs for two pages of paper.

16 https://www.bls.gov/oes/current/oes_nat.htm; wages as a percent of total compensation from the Employer Cost for Employee Compensation (20202020, Bureau of Labor Statistics http://www.bls.gov/news.release/ecec.t02.htm); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 20192019 (Employment Costs Index data for private industryhttp://www.bls.gov/news.release/eci.nr0.htm).

Changes in the estimates for external review costs and the rate of external review requests also impacted the expected burden. The hour and cost burdens have been updated based on improved estimates of the costs associated with external review, and the rate of external review. For example, the external review rate used to determine the expected number of external reviews was .03%. This rate was based on the Office of Personnel Management's experience in operating the Federal Employee Health Benefit Plan (FEHBP). However, since OPM is no longer administering the HHS federal external review program, we have updated our rate based on data from states which conduct external reviews such as data from the state of North Carolina, which we believe provides a more accurate approximation of the rate at which consumers request external reviews. Based on these adjustments and external reviews for grandfathered plans, the estimated annual responses have increased from 516,626,544 to 517,014,153 (516,626,544+381,826+5,783).

16. Publication/Tabulation Dates

There are no plans to publish the outcome of the information collection.

17. Expiration Date

The collection of information will display a valid expiration date and OMB control number.