DEPARTMENT OF LABOR

Employee Benefits Security Administration

Agency Information Collection Activities; Request for Public Comment

AGENCY: Employee Benefits Security Administration (EBSA), Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. Currently, the Employee Benefits Security Administration (EBSA) is soliciting comments on No Surprises Act: IDR Process, Affordable Care Act Internal Claims and Appeals and External Review Procedures for ERISA Plans, and Opt-in State Balance Bill Process. A copy of the information collection request (ICR) may be obtained by contacting the office listed in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office shown in the **ADDRESSES** section on or before [Insert date 60 days from publication]

ADDRESSES: James Butikofer, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N– 5718, Washington, DC 20210, or ebsa.opr@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Current Actions

This notice requests public comment pertaining to the Department's request for extension of OMB's approval of the Application. After considering comments received in response to this notice, the Department intends to submit an ICR to OMB for continuing approval. No change to the existing ICR is proposed or made at this time. The Department notes that an agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a valid OMB control number. A summary of the ICR and the current burden estimates follows:

Agency: Employee Benefits Security Administration, Department of Labor.

Title: No Surprises Act: IDR Process.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210-0169.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 22,257.

Frequency of Responses: On occasion.

Responses: 36,675.

Estimated Total Burden Hours: 65,948.

Estimated Total Burden Cost (Operating and Maintenance): $187,546.

Description:

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was signed into law. The No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently. The CAA added provisions applicable to group health plans and health insurance issuers in the group and individual markets in a new Part D of title XXVII of the Public Health Service Act (PHS Act) and also added new provisions to part 7 of the Employee Retirement Income Security Act (ERISA), and Subchapter B of chapter 100 of the Internal Revenue Code (Code).

Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A-1, which contain limitations on cost sharing and requirements for initial payments for emergency services. In addition, Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A-1 to establish a Federal independent dispute resolution (Federal IDR) process that nonparticipating providers or facilities and group health plans and health insurance issuers in the group and individual market may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for certain services. More specifically, the Federal IDR provisions may be used to determine the out-of-network rate for certain emergency services, nonemergency items and services furnished by nonparticipating providers at participating health care facilities, where an All-Payer Model Agreement or specified state law does not apply. Finally, Section 105 of the No Surprises Act created Code section 9817, ERISA section 717, and PHS Act section 2799A-2 which contain limitations on cost sharing and requirements for initial payments for air ambulance services, and allow plans and issuers and providers of air ambulance services to access the Federal IDR process.

The Federal IDR process requires a number of disclosures from plans, issuers, FEHB carriers, and nonparticipating providers or nonparticipating emergency facilities.

Before accessing the Federal IDR process to determine the out-of-network rate for a qualified item or service, the parties must engage in a 30-business-day open negotiation period to attempt to reach an agreement regarding the total out-of-network rate (including any cost sharing). To initiate the open negotiation period, the initiating party must provide notice to the other party within 30 business days of the receipt of initial payment or notice of denial of payment for the qualified item or service. The open negotiation notice must include information sufficient to identify the items or services subject to negotiation, including the date the item or service was furnished, the service code, the initial payment amount or notice of denial of

payment, as applicable, an offer for the out-of-network rate, and contact information of the party sending the open negotiation notice.

When the parties do not reach an agreed upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process by submitting the Notice of IDR Initiation to the other party and to the Departments during the 4-business day period beginning on the 31st business day after the start of the open negotiation period. If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing notice to the Departments of initiation of the Federal IDR process, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if selected) electronically through the Federal IDR portal, in a form and manner specified by the Departments, as soon as possible, but no later than 3 business days after the date of the agreement. This notification should include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility select a certified IDR entity, or if they fail to select a certified IDR entity, they must notify the Departments of their selection no later than 1 business day after such selection or failure to select. To the extent the non-initiating party does not believe that the Federal IDR process applies, the non-initiating party must also provide information that demonstrates the lack of applicability by the same date that the notice of selection or failure to select must be submitted. If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range) through a random selection method.

Additionally, no later than 10 business days after the date of selection of the certified IDR entity with respect to a payment determination for a qualified IDR item or service, the provider or facility and the plan or issuer must submit to the certified IDR entity an offer for a payment amount for the qualified IDR item or service furnished by such provider or facility though the Federal IDR portal. After the selected certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider or facility and the plan, issuer, or FEHB carrier of the payment determination and the reason for such determination, in a form and manner specified by the Departments.

If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on the permitted considerations, with respect to the qualified IDR item or service.

On October 7, 2021, the Office of Management and Budget (OMB) approved the information collection request (OMB Control Number 1210-0169) under the emergency procedures for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35) and 5 CFR 1320.13. The approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for ERISA Plans.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210-0144.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 2,524,241.

Frequency of Responses: On occasion.

Responses: 381,826.

Estimated Total Burden Hours: 3,241.

Estimated Total Burden Cost (Operating and Maintenance): $1,627,679.

Description:

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 interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503-1 (the 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.

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 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.

On October 7, 2021, the Office of Management and Budget (OMB) approved the information collection request (OMB Control Number 1210-0144 under the emergency procedures for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35) and 5 CFR 1320.13. The approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Opt-in State Balance Bill Process.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210-0168.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 103.

Frequency of Responses: On occasion.

Responses: 103.

Estimated Total Burden Hours: 155.

Estimated Total Burden Cost (Operating and Maintenance): $54.

Description:

The No Surprises Act was enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260). The interim final rules allow plans to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)-(d) of the Code, section 716(a)-(d) of ERISA, and section 2799A-1(a)-(d) of the PHS Act. A plan that has chosen to opt into a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into a specified state law, identify the state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

On September 22, 2021, the Office of Management and Budget (OMB) approved the information collection request (OMB Control Number 1210-0168 under the emergency procedures for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35) and 5 CFR 1320.13. The approval is scheduled to expire on March 31, 2022.

II. Focus of Comments

The Department is particularly interested in comments that:

- Evaluate whether the collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the collections of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., by permitting electronic submissions of responses.

• Evaluate the effectiveness of the additional demographic questions.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the information collection; they will also become a matter of public record.

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Signed at Washington, DC, this 29th day of October, 2021.

Ali Khawar,

Acting Assistant Secretary,

Employee Benefits Security Administration,

U.S. Department of Labor.

[FR Doc. 2021-24497 Filed: 11/8/2021 8:45 am; Publication Date: 11/9/2021]