DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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OFFICE OF THE ADMINISTRATOR

DATE: October 5, 2021

TO: Sharon Block
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

SUBJECT: Request for Emergency Clearance of Updates to the External Review Paperwork Reduction Act Package for Information Collection Requirements Related to Surprise Billing; Part II; External Review Provisions (CMS-9908-IFC), OMB 0938-AU62

Emergency Justification

The Department of Labor (DOL), Department of Health and Human Services (HHS), Department of the Treasury (the Departments), and the Office of Personnel Management (OPM), in compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA), request an emergency review and approval of updates to the previously approved External Review PRA information collection request (1210-0144) to begin collecting information that is essential to implementing requirements under the No Surprises Act (NSA). While the previous PRA package did not apply to grandfathered plans, the NSA requirements will apply to grandfathered plans, as described under the September 2021 IFR, for plan years beginning on or after January 1, 2022. The use of the normal PRA procedures is likely to prevent the Departments 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 NSA. 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.

The NSA was enacted on December 27, 2020, as title I of Division BB of the Consolidated Appropriations Act (CAA), 2021.[1] The external review provisions in the NSA expand consumer protections from surprise medical bills and apply for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The use of the normal PRA procedures is likely to prevent the Departments from collecting information that will be essential to meeting the

[1] Text - H.R.133 - 116th Congress (2019-2020): Consolidated Appropriations Act, 2021 | Congress.gov | Library of Congress

effective dates of the NSA and 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.

Additionally, the information collection in this PRA submission is in the interim final rules titled "Requirements Related to Surprise Billing; Part II" (September 2021 IFR). The Departments waived proposed rulemaking for that rule, including the ICRs, because it is in the public interest to promulgate interim final rules and it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before the interim final rules become effective. The same justification for waiving proposed rulemaking applies to emergency review and approval of the PRA submission on the independent dispute resolution (IDR) provisions and protections for the uninsured in the NSA and it also applies to this updated PRA package. Emergency approval of this updated PRA package ICRs is a vital step in implementing the consumer protections intended by passage of the NSA.

Background

The CAA, which includes Section 110 of the No Surprises Act, adds 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 under section 2799A-1 or 2799A-2 of the PHS Act. The publication of the September 2021 IFR implements certain provisions of the CAA, including Section 110 which requires that external review processes apply to items and services subject to determinations involving 2799A-1 or 2799A-2 of the PHS Act.

The September 2021 IFR broadens the scope of existing external review requirements at 45 CFR 147.136 to 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 2799A-1 or 2799A-2 is eligible for external review. Additionally, under the September 2021 IFR, the external review requirements are newly applied to grandfathered health plans for adverse benefit determinations involving items and services covered by requirements of PHS Act section 2799A-1 or 2799A-2, as added by the CAA of 2021. The definitions of group health plan and health insurance issuer that are cited in section 110 of the NSA include both grandfathered and non-grandfathered plans and coverage. Accordingly, the practical effect of section 110 of the NSA is that grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections. Grandfathered and non-grandfathered plans must comply either with a state external review process or a federal review process.

The PRA amendments focus on ICRs related to the Departments requirements under the September 2021 interim final rules. Based on the legislative and regulatory authority outlined above, the ICRs advance the legislative goals of the NSA. Emergency approval of the PRA submission will enable the Departments to expand patient protections regarding surprise medical billing, without delay, specifically by providing patient access to the external review process for adverse benefit determinations.

We intend to publish the interim final regulation on October 7, 2021. This Emergency processing request under the PRA is being requested on the same basis that good cause was found by the Departments to issue these interim final rules. The Departments have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until after a full public notice and comment process has been completed. Although this effective date may have allowed for the regulations, if promulgated with the full notice and comment rulemaking process, to be applicable in time for the applicability date of the provisions in the NSA, this timeframe would not provide sufficient time for the regulated entities to implement the requirements. In addition to implementing external review protections under NSA Section 110, the interim final rules establish a federal independent dispute resolution process for health plans, providers, and facilities in addition to a patient-provider dispute resolution process for uninsured (or self-pay) individuals. The same justification for waiving proposed rulemaking applies to emergency review and approval of the PRA submission on the independent dispute resolution (IDR) provisions and protections for the uninsured in the NSA. It also applies to this updated PRA package. The NSA requires that the external review protections and independent dispute resolution processes are effective on the same day as the NSA provisions implemented in the interim final rule with request for comments, "Requirements Related to Surprise Billing; Part I".