DEPARTMENT OF HEALTH & HUMAN 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 the Paperwork Reduction Act Package for Information Collection Requirements Related to Surprise Billing; Part II; (CMS-9908-IFC), OMB 0938-AU62

Emergency Justification

The Department of Labor (DOL), Department of Health and Human Services (HHS), and the Department of the Treasury (the Departments) and the Office of Personnel Management (OPM), seek an emergency review and approval of the Paperwork Reduction Act (PRA) requirements related to the information collection requests (ICR) regarding implementation of the No Surprises Act (NSA). As explained in more detail below, we believe this process is warranted for a variety of reasons under 5 CFR 1320.13(a).

The NSA was enacted on December 27, 2020, as title I of Division BB of the Consolidated Appropriations Act, 2021.[1] The independent dispute resolution (IDR) provisions and protections for the uninsured in the NSA 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 effective dates of the NSA. For example, in order to meet the statutory requirements, the Departments need to begin collecting eligibility data from potential IDR or selected dispute resolution (SDR) entities for certification including level of expertise and staffing, conflicts of interest disclosures, accreditation, confidentiality practices, list of fees, appropriate fiscal integrity indicators, among other information. The Departments need to collect this information and begin certifying IDR and SDR entities in fall of 2021 in order to establish the necessary IDR and SDR entities and related contracts, and implement the federal IDR process by January 1, 2022.

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

Additionally, the information collection in this PRA submission is in the interim final rule, "Requirements Related to Surprise Billing; Part II." 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. Emergency approval of the PRA package ICRs is a vital step in implementing the consumer protections intended by passage of the NSA.

Background

The provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), and PHS Act sections 2799A-1(c) and 2799A-2(b), as added by sections 103 and 105 of the NSA, establish a federal IDR process that nonparticipating providers or facilities, nonparticipating providers of air ambulance services, 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. The federal IDR process 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, as well as for air ambulance services furnished by nonparticipating providers of air ambulance services.

Under the NSA, upon receiving an initial payment or notice of denial of payment from a plan or issuer, the health care provider or plan or issuer may initiate an open negotiation period. If the parties cannot agree on an out-of-network rate, either party may initiate the federal IDR process and may jointly select a certified IDR entity, or, if the parties do not select a certified IDR entity, the Departments will do so. The NSA specifies that the certified IDR entity selected cannot be a party to the determination or their employee or agent, have a material familial, financial, or professional relationship with such party, or otherwise have a conflict of interest.

In resolving the disputes through the federal IDR process, the NSA provides that each party must submit to the certified IDR entity an offer for a payment amount for the item or service in dispute and other information as requested by the certified IDR entity. The IDRE must determine the amount of payment under the plan or coverage for such item or service as furnished by such provider or facility, in accordance with factors set out by the NSA and subsequent regulations. The NSA also sets out requirements for certification of IDR entities by the Departments. To be certified, IDR entities must provide written documentation demonstrating that they meet the eligibility criteria. The interim final rules require certified IDR entities submit information related to the federal IDR process, in order to allow the Departments to quarterly publish information on IDR determinations.

Additionally, the NSA includes provisions that require health care providers and health care facilities to furnish good faith estimates upon request or upon scheduling items or services to uninsured (or self-pay) individuals. In order to implement these good faith estimate provisions under PHS Act section 2799B-6(1) and 2799B-6(2)(B), as added by section 112 of the NSA, HHS is adding 45 CFR 149.610 to establish requirements for providers and facilities to

specifically inquire about an individual's health coverage status, notify individuals of the ability to receive a good faith estimate and establish requirements for providing a good faith estimate.

PHS Act section 2799B-6(2) and these interim final rules specify that a provider or facility must provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such items or services (including any items or services that are reasonably expected to be provided in conjunction with such scheduled items or services and such items or services reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes (i.e., ICD, CPT, HCPCS, and/or DRG codes) for any such items or services. The definitions related to good faith estimates of expected charges for uninsured (or self-pay) individuals for scheduled items and services and upon request, requirements for the providers and facilities, timing, and good faith estimate content requirements are set forth in PHS Act section 2799B-6 and implementing regulation at 45 CFR 149.610, established under these interim final rules.

PHS Act section 2799B-7, as added by section 112 of the NSA, provides further protections for uninsured (or self-pay) individuals by requiring the Secretary of HHS to establish a process (in this section referred to as patient-provider dispute resolution) under which an uninsured (or self-pay) individual who received from a provider or facility, a good faith estimate of the expected charges, and who, after being furnished the item or service, is billed for charges that are substantially in excess of the estimate, may seek a determination from a SDR entity of the amount of charges to be paid. HHS is adding new 45 CFR 149.611 to implement this patient-provider dispute resolution process including specific definitions related to the patient-provider dispute resolution process. HHS is also codifying provisions related to: eligibility for the federal patient-provider dispute resolution process; selection of a SDR entity; fees associated with this section; certification of SDR entities; and deferral to state patient-provider dispute resolution processes.

The PRA submission focuses 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 implement, without delay, a federal IDR process for providers (including air-ambulance providers), a federal patient-provider dispute resolution process, and requirements for a good faith estimate.

We intend to publish the interim final regulation on September 30, 2021. This Emergency processing request under the PRA is being requested on the same basis that good cause was found by the Departments and the OPM Director to issue these interim final rules. The Departments and OPM 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. We do not anticipate significant concerns from the vast majority of stakeholders as the public will welcome the consumer protections established through the implementation of these provisions. 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 NSA requires that these 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”. While health care providers, facilities, and plan issuers may react negatively to some of the additional requirements, there is general support for the provisions and implementation of the NSA.