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Office of Management and Budget (OMB)

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Subject: Non-Substantive Change Request – Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in (OMB# 0938-1401)

This memo requests approval of a non-substantive change to the Standard Notice and Consent documents in the information collection "Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in" (OMB# 0938-1401).

BACKGROUND

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA),[1] which included 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 and balance billing under many of the circumstances in which surprise bills arise most frequently.

The July 13, 2021 interim final rules "Requirements Related to Surprise Billing; Part I" (86 FR 36872, henceforth the July 2021 interim final rules) issued by the Department of Health and Human Services (HHS), Department of Labor (DOL), the Department of the Treasury (collectively, the Departments), and the Office of Personnel Management (OPM) implement provisions of the No Surprises Act that apply to group health plans, health insurance issuers offering group or individual health insurance coverage, and carriers in the Federal Employees Health Benefits Program that provide protections against balance billing and out-of-network cost sharing with respect to emergency services, non-emergency services furnished by nonparticipating providers related to patient visits to certain types of participating health care facilities, and services furnished by nonparticipating providers of air ambulance services. The July 2021 interim final rules prohibit nonparticipating providers, emergency facilities, and providers of air ambulance services from balance billing participants, beneficiaries, and enrollees in certain situations unless they satisfy certain notice and consent requirements. The requirements related to the notice and consent, applicable exceptions to when consent may be sought, and timing are set forth in section 2799B-2 of the PHS Act and implemented at 45 CFR 149.410 and 45 CFR 149.420 of the July 2021 interim final rules. The consent form must document the time and date on which the participant, beneficiary, or enrollee received the written notice and the time and date on which the individual signed the consent to be furnished such items or services by the nonparticipating provider.

[1] Pub. L. 116-260.

The Standard Notice and Consent form, as previously approved, inadvertently omitted a key data element in the consent section. Specifically, the bracketed instruction on page six reads "[enter date of notice]," which did not capture the time data element. Because use of this form is required, it is essential that the form contains all required data elements as specified in the applicable regulations.

The collection was last approved by OMB on December 22, 2025, and expires on December 31, 2028. A revised Paperwork Reduction Act package (PRA package) containing this collection was submitted to OMB as part of the Federal Independent Dispute Resolution Operation final rule (CMS-9897)[2] for approval.

OVERVIEW OF REQUESTED CHANGES

Subsequent to OMB's approval on December 22, 2025, and following submission of the PRA package associated with the Federal Independent Dispute Resolution Operation final rule the Centers for Medicare and Medicaid Services (CMS) has updated the Standard Notice and Consent form – specifically, third bullet on page six – to revise the bracketed language to read "[enter **time and** date of notice]." This change was made to comply with the requirement that the consent form must document the time and date on which the participant, beneficiary, or enrollee received the written notice from the nonparticipating provider. Without this change, CMS is unable to consistently enforce the requirement to record both the time and date when the notice was provided to the participant, beneficiary, or enrollee. In some instances, the time when the notice was received determines whether or not the consent is valid. This omission has impacted enforcement casework, as providers using the form have lacked clear instruction to document the required time element.

This non-substantive change request is to implement this minor correction and replace the current Standard Notice and Consent form with the updated version. There are no other changes being made at this time, and there are no program changes or burden adjustments. CMS is also requesting approval of this change in conjunction with the PRA package currently awaiting OMB approval.

[2] 91 FR 33900