<u>Supporting Statement – Part A</u> <u>Complaints Submission Process under the No Surprises Act</u> (CMS-10779/OMB control number 0938-NEW)

A. Background

Enacted on December 27, 2020, the No Surprises Act, which was enacted as part of the Consolidated Appropriations Act (CAA), amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), and the Internal Revenue Code of 1986 (Code). The No Surprise Act implements provisions that protect individuals from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances. Additionally, the No Surprises Act sets forth a complaints processes with respect to potential violations of balance billing requirements set forth in the No Surprises Act.

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 medical bills arise most frequently. The 2021 interim final regulations "Requirements Related to Surprise Billing; Part I" (86 FR 36872, 2021 interim final regulations) issued by the Departments of Health and Humans Services (HHS), Department of Labor (DOL), the Department of Treasury (collectively, the Departments), implement provisions of the No Surprises Act that apply to group health plans, health insurance issuers offering group or individual health insurance coverage that provide protections against balance billing and out-of-network cost sharing with respect to emergency services, non-emergency services furnished by nonparticipating providers at certain participating health care facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services.

The No Surprises Act and the 2021 interim final regulations directs the Departments of Labor, Health and Human Services, and the Department of Treasury (collectively, "the Departments") to establish a process to receive complaints regarding violations of the application of qualifying payment amount (QPA) requirements by group health plans and health insurance issuers offering group or individual health coverage. The No Surprises Act also directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services regarding balance billing requirements and to respond to such complaints within 60 days. 3,4

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 of the information collection request related to provisions in 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.

¹Pub. L. 116-260 (Dec. 27, 2020).

²Internal Revenue Code (Code) section 9816(a)(2)(B)(iv), ERISA Section 716(a)(2)(B)(iv) and PHS Act section 2799A- (a)(2)(B)(iv).

³PHS Act section 2799B-4(b)(3).

⁴PHS Act section 2799B-1, 2799B-2, 2799B-3, and 2799B-5.

B. Justification

1. Need and Legal Basis

The No Surprises Act directs the Departments to establish a process to receive complaints regarding violations of the application of QPA requirements by group health plans and health insurance issuers offering group or individual health coverage. The No Surprises Act also directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services regarding balance billing requirements and to respond to such complaints within 60 days.

2. Information Users

CMS will request information from non-federal governmental plans and issuers, health care providers, facilities, providers of air ambulance services, and individuals to review and process a complaint for potential violations of balance billing requirements.

3. <u>Use of Information Technology</u>

Plans and issuers, health care providers, facilities, providers of air ambulance services, and individuals (consumers and authorized representatives) may submit some or all information electronically to CMS.

4. <u>Duplication of Efforts</u>

The No Surprises Act amended ERISA, the Code, and the PHS Act. However, only CMS oversees non-Federal governmental health plans and issuers of individual and group health insurance coverage, therefore there will be no duplication of effort with DOL and the Treasury. States may request or require issuers to provide information as well. However, no duplication should occur because CMS will only request information from issuers when CMS has direct enforcement responsibility for the No Surprises Act in a state.

5. Small Businesses

Small businesses are not significantly affected by these information collection requirements.

6. Less Frequent Collection

This collection is required to fulfill the statutory requirements in the No Surprises Act. CMS will not be able to conduct reviews of balance billing complaints and ensure regulatory compliance without first collecting the information from complainants, and by collecting additional information needed from non-federal governmental plans and issuers, health care providers, facilities, providers of air ambulance services, and individuals.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

An interim final rule with requests for comment (86 FR 36872) published on July 13, 2021. HHS also consulted with external stakeholders to obtain information on consumer impact and burden in information collection. Specifically, HHS consulted with consumers, providers, consumer advocates, and other professional organizations to consider the impact of information collection for complaints.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these ICRs.

10. Confidentiality

The No Surprises Act does not require CMS to share information on findings of compliance and noncompliance of balance billing violations.

11. Sensitive Questions

These ICRs involves sensitive questions that may obtain personally identifiable information and personal health information..

12. Burden Estimates (Hours & Cost)

HHS estimates that there will be, on average, 3,600 balance billing complaints against providers, facilities, providers of air ambulance services, plans, and issuers submitted annually. HHS estimates that it will take each complainant 30 minutes (at an hourly rate of \$54.14) to collect all relevant documentation related to the alleged violation and to access and complete the provided complaint form, with an equivalent cost of approximately \$27. The total burden for all complainants is estimated to be 1,800 hours, with an equivalent annual cost of approximately \$97,452. As DOL, the Department of Treasury and HHS share jurisdiction, HHS will account for 50 percent of the burden, approximately 900 burden hours with an equivalent cost of approximately \$48,726.

TABLE 1: Annual Burden and Costs for Complaints Related to Surprise Billing

| Estimated Number of Respondents | Estimated Number of Responses | Burden Per Response (Hours) | Cost per Response | Total Annual Burden (Hours) | Total Estimated Cost |
|---------------------------------------|-------------------------------------|--------------------------------------|----------------------|--------------------------------------|----------------------------|
| 1,800 | 1,800 | 0.5 | \$27.07 | 900 | \$48,726 |

 $^{\rm 6}$ We use the average wage rate for all occupations.

14. Cost to Federal Government

Costs to the federal government to build a system to receive complaints, and expand existing systems, estimated to be one-time costs of approximately \$17.2 million in 2021; and ongoing costs to process complaints, estimated to be approximately \$10.2 million in 2022, \$10.4 million in 2023 and \$10.6 million in 2024 and subsequent years.

15. Changes to Burden

This is a new collection of information.

Table 2 includes a summary of the burden related to the ICR and the burden accounted for by each Department.

TABLE 2: Summary of Annual Burden Estimates

| Regulation Section | ICR Title | Model Instrument | Percentage of Shared Burden | Shared Burden Hours |
|--------------------------------|--|---------------------|---|---|
| 45 CFR 149.150, 45 CFR 149.450 | Complaints Process for Surprise Medical Bills | No [†] | HHS - 50; DOL – 25; Department of Treasury - 25 | HHS- 900; DOL – 450; Department of Treasury– 450. |

^{† -} The model instrument will be included in the 60-day package.

16. Publication/Tabulation Dates

CMS is not required to publish reports.

17. Expiration Date

The expiration date and OMB control is displayed on the associated instrument.