POWERS

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ATTORNEYS AT LAW

MEMORANDUM

From: **Peggy Tighe, Julie Allen, Peter Thomas, Jeremy Lewin, and Michaela Boudreaux**

Date: **January 12, 2022**

Re: **No Surprises Act Implementation and Litigation**

In December 2020, Congress passed, and President Trump signed the *No Surprises Act* (Title I of Division BB of the Consolidated Appropriations Act, 2021), a law designed to provide customer protections against surprise medical bills. Unanticipated billing arises when consumers receive care from out-of-network hospitals, doctors, and/or other providers. This situation most often occurs in emergencies when patients have little ability to dictate where they receive care and when patients receive care at an in-network hospital but a secondary provider, such as an anesthesiologist, is out-of-network.

The *No Surprises Act*, effective January 1, 2022, requires the Department of Health and Human Services (HHS), together with the Departments of Labor, Treasury, and Office of Personnel Management (OPM), to publish regulations that restrict surprise billing for patients in job-based and individual health plans, provide additional protections against surprise medical bills, and implement new requirements for group health plans and issuers to submit certain information about prescription drug and health care spending. The first rule, published on July 13, 2021 and entitled "Requirements Related to Surprise Billing; Part I", is part one of a three-part rulemaking process. The second rule was published on October 7, 2021 and entitled "Requirements Related to Surprise Billing; Part II," while a third interim final rule entitled "Prescription Drug and Health Care Spending" was released on November 23, 2021. In addition, a proposed rule dedicated to Air Ambulance Services was released on September 16, 2021.

The law and rules have been criticized by many provider organizations throughout the Congressional and rule-making process, with five pending lawsuits arising because of the law. Due to the number of concerns and lawsuits, it is unlikely that Congress will act to amend the law until the courts address the pending cases. More information on the *No Surprises Act*, the three interim final rules, the proposed rule, and the pending lawsuits can be found below.

I. Overview of *No Surprises Act*

Background

Congress worked to address surprise billing for years after numerous reports from patients about unexpected and financially crippling medical bills. According to the Kaiser Family Foundation, among privately insured patients, an estimated 1 in 5 emergency claims and 1 in 6 in-network hospitals include at least one out-of-network bill. Additionally, plans may only pay for a portion of it and leave the patient liable for balance billing.

Key Provisions

The *No Surprises Act* includes the following key provisions:

- Health plans are responsible for covering surprise medical bills for emergency services and provider bills for services received at in-network hospitals and other facilities.
- Medical bills must be covered without prior authorization and in-network cost sharing applies.
- External appeal rights are applicable if a consumer believes that their health plan has not identified or covered a surprise medical bill.
- Emergency services provided by out-of-network providers are not allowed to balance bill patients.
- Out-of-network providers cannot send patients bills for an amount that is more than the in-network cost sharing for the services.
- HHS, the Department of Labor, and the Department of Treasury are required to establish a process for receiving complaints regarding violations of surprise billing protections.
- Enacts an independent dispute resolution process (IDR) for any surprise medical bill following a 30-day period when the plan and provider plan to negotiate a payment amount.
- Requires a good faith estimate for the cost of goods and services to be provided to any patient without insurance, or a patient electing not to use insurance.

The *No Surprises Act* also includes provisions specific to health plans and price transparency. Health plans are required to provide an expanded explanation of benefits and must provide continuity of coverage when a provider leaves the network. Additionally, health plans must establish a process to update their provider directory information every 90 days. A detailed section-by-section summary is available here.

II. Implementation

A. Overview of Requirements Related to Surprise Billing; Part I

Background

HHS, the Department of Labor, and the Department of Treasury, along with OPM released an interim final rule with a comment period on July 13, 2021. Requirements Related to Surprise Billing; Part I implements the requirements in the *No Surprises Act* for group health plans, health insurance carriers, carriers under the Federal Employees Health Benefits Program, health care providers, and air ambulance service providers. The provisions in the rule are applicable for plan years and policy years beginning on or after January 1, 2022. The fact sheet and more information is available here.

Key Provisions

The rule includes the following key provisions:

- Requires emergency services to be covered without any prior authorization, regardless of whether the provider is an in-network provider or an in-network emergency facility, and regardless of any other term or condition of the plan or coverage other than the exclusion or coordination of benefits, permitted affiliation, or waiting period.
- Specifies methodology for calculating cost-sharing amounts for emergency services provided by out-of-network emergency facilities and out-of-network providers, and services by out-of-network providers at in-network facilities.
- Details that out-of-network rates are based on All-Payer Model Agreements under section 1115A of the Social Security Act, state law, or an amount agreed upon by the plan or issuer and the provider or facility. If none of the three conditions apply, then the amount is determined by an IDR entity.
- Requires health care providers and facilities to make updates to their websites and provide a one-page notice about any applicable state balance billing limitations or prohibitions, requirements, and prohibitions applicable under Public Health Service Act sections 2799B-1 and 2799B-2, and how to contact state and federal agencies in the event of a violation of the stated consumer protections.
- Establishes a consumer complaints process regarding violations by providers, facilities, and providers or air ambulances services.

B. Overview of Requirements Related to Surprise Billing; Part II

Background

HHS, the Department of Labor, and the Department of Treasury, along with OPM released an interim final rule with a comment period on October 7, 2021. Requirements Related to Surprise Billing; Part II establishes protections from surprise billing and excessive cost sharing for consumers receiving health care items and services. The regulations outlined in the rule are applicable to group health plans and health insurance issuers for plan and policy years beginning on or after January 1, 2022. In combination with the rule, HHS also launched a website for providers and patients to find general information about the No Surprises Act. The fact sheet and more information is available here.

Key Provisions

The rule includes the following key provisions:

- Establishes the federal IDR process that out-of-network providers, facilities, air ambulance services, plans, and issuers in the group and individual market may use to determine the out-of-network rate.
- Dictates that disputing parties must begin a 30-day open negotiation period to determine the payment rate and must jointly select a certified IDR entity.
- Explains that parties must submit their offers for payment along with supporting document after the IDR entity is selected.

The rule also contains a detailed reasoning for requiring a provider or facility to supply a good faith estimate amount explaining the amount that the provider or facility may charge the individual for services. Goods and services that are reasonably expected to be provided are also required to be disclosed. HHS argues that an individual cannot consent to waive balance billing and cost-sharing protections unless they have been fully informed as to both the facility and provider charges. HHS acknowledges that it may take time for providers and facilities to develop systems and processes for providing and receiving the good faith estimate. To allow time for the transition, HHS will exercise discretion in situations where a good faith estimate supplied to an uninsured individual does not include all expected charges for other providers that are involved in the individual's care from January 1-December 31, 2022.

The rule establishes a patient-provider dispute resolution in an instance where an uninsured individual is billed for an amount that is greater than the good faith estimate. "Substantially in excess" is defined as the billed charges being at least $400 more than the good faith estimate for any provider or facility listed on the estimate.

C. Overview of Prescription Drug and Health Care Spending

Background

HHS, the Department of Labor, and the Department of Treasury, along with OPM released an interim final rule on November 23, 2021 entitled "Prescription Drug and Health Care Spending." The rule implements requirements for health plans and issuers in the group and individual market to submit information about prescription drug and health care spending. The information will be used to develop a report on prescription drug pricing trends and the impact on premiums and out-of-pocket costs starting in 2023. Plans were required to start submitting the necessary information by December 27, 2021. Comments on the rule are required before 5PM on January 24, 2022. The fact sheet is available here.

Key Provisions

Health insurance plans and issuers are required to submit the following information to the federal government:

- General information about the plan and coverage including enrollment and premium information;

- Total health care spending broken down by cost type including hospital care, primary care, prescription drugs, and other medical costs;
- The most frequently dispensed brand name drugs, the costliest drugs, and the prescription drugs with the greatest increase in plan or coverage expenditures;
- Prescription drug rebates and fees paid by drug manufacturers; and
- The impact of prescription drug rebates, fees, and other renumeration on premiums and out-of-pocket costs.

D. Overview of Reporting Requirements Regarding Air Ambulance Services

Background

HHS, the Department of Labor, and the Department of Treasury, along with OPM released a notice of proposed rulemaking on September 16, 2021 entitled "Reporting Requirements Regarding Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement." The proposed rule would establish new reporting requirements regarding air ambulance services, disclosure and reporting requirements on issuers of individual health insurance coverage, and new procedures for enforcement of Public Health Services Act provisions against facilities and providers of air ambulance services. Written comments were required by October 18, 2021. The fact sheet is available here.

Key Provisions

The proposed rule contains the following provisions:

- Requires data collection from providers, plans, and issuers regarding air ambulance services.
- Instructs plans, issuers, and providers of air ambulance services to submit data for each claim and transport for the two years covered by the reporting requirements in the No Surprises Act, which HHS and the Department of Transportation will use to produce a comprehensive report on air ambulance services.
- Requires issuers offering individual health insurance coverage or short-term, limited duration plans to disclose commission rates and the compensation provided to an agent or broker associated with enrolling the individual.
- Extends Centers for Medicare and Medicaid Services process for determining whether a state is not enforcing the Public Health Services Act requirements, creates a process for initiating investigations in the event of a violation, and codifies the process outlined in the Public Health Services Act for civil penalties of up to $10,000 per violation.

III. Litigation

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There are several active lawsuits against the Biden Administration related to the No Surprises Act:

- The Texas Medical Association filed a complaint on October 28, 2021, in the United States District Court for the Eastern District of Texas.[1]
- The Association of Air Medical Services filed a complaint on November 16, 2021, in the United States District Court for the District of Columbia.
- The American Medical Association and the American Hospital Association filed a complaint on December 9, 2021, in the United States District Court for the District of Columbia.[2]
- The American Society of Anesthesiologists, American College of Radiologists and American College of Emergency Physicians filed a complaint on December 22, 2021, in the United States District Court for the Northern District of Illinois.[3]
- A New York based surgery group and individual acute care surgeon filed a complaint on December 31, 2021, in the United States District Court for the Eastern District of New York.

A common theme of the complaints is a challenge to a provision of the insurer-provider dispute resolution process of the interim final rule. The provision instructs dispute resolution entities to presume an insurer's median in-network rate is the appropriate rate for out-of-network services and limits how and when a dispute resolution entity may consider other factors in resolving payment disputes between insurers and providers.

The plaintiffs argue this instruction deviates from the plain language of the law and unfairly favors insurers. They assert the law passed by Congress directed that the dispute resolution entity must consider all information submitted by the physician and the insurer, without a presumption in favor of any one factor.

The primary relief requested by the plaintiffs in these matters is to set aside only certain provisions of the interim final rule related to the dispute resolution process. If granted, this relief would not invalidate the No Surprises Act. Notably, the medical association plaintiffs in the above matters have confirmed support for the patient protections offered by the Act.

[1] The TMA case also includes an individual physician plaintiff based in Texas.
[2] Other plaintiffs in the AMA/AHA case are Renown Health, UMass Memorial Healthcare, Inc., and two physicians based in North Carolina.
[3] Powers represents ASA, ACR and ACEP in this matter.

IV. Appendix

Rule	Type	Date Issued	Date Effective
Requirements Related to Surprise Billing; Part I	Interim Final Rule	July 13, 2021	September 13, 2021
Requirements Related to Surprise Billing; Part II	Interim Final Rule	October 7, 2021	October 7, 2021
Prescription Drug and Health Care Spending	Interim Final Rule	November 23, 2021	December 23, 2021
Air Ambulance Services	Proposed Rule	September 16, 2021	Comments Required by October 18, 2021