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Legislative Update

By Robert M. Schechter and David E. Sklar

No Surprises Act and the Provider/Patient/Payor Dynamic Backdrop

Robert M. Schechter
Porzio, Bromberg & Newman, PC
Morristown, N.J.

David E. Sklar
Porzio, Bromberg & Newman, PC
Morristown, N.J.

Robert Schechter is a principal and David Sklar is an associate with Porzio, Bromberg & Newman, PC in Morristown, N.J.

With the start of 2022, new U.S. laws and regulations impacting medical billing practices for out-of-network services went into effect. These changes are the result of legislation known as the No Surprises Act and subsequently established regulations relating to its implementation. According to the Centers for Medicare and Medicaid Services, "[t]he No Surprises Act protects people covered under group and individual health plans from receiving surprise medical bills when they receive most emergency services, non-emergency services from out-of-network providers at in-network facilities, and services from out-of-network air ambulance service providers."[1]

Protecting Americans from unanticipated medical bills not covered by insurance carriers is a goal that has received bipartisan support; however, as health care industry professionals know, the state of affairs that surrounds surprise medical bills is not a simple provider/patient dynamic, but rather a complex marketplace also shaped by behemoth players including government and insurance payors that impact the context in which the provider/patient relationship takes place. Health care providers, businesses, insurers and industry professionals are now paying close attention to the real-world implications of the No Surprises Act and related regulations, which have been the subject of intense lobbying and, in recent months, have also become the subject of litigation.

On Dec. 27, 2020, President Donald J. Trump signed into law the Consolidated Appropriations Act of 2021 (CCA), which contained, among other things, the No Surprises Act. As most Americans are aware, medical bills not covered by insurance carriers can be a significant source of financial hardship for American families. A study conducted by the *American Journal of Public Health* found that 58.5 percent of a sample population of 910 bankruptcy filers cited medical expenses as a contributing factor to their bankruptcy.[2] Unexpected medical bills, which often result from full or partial denial of coverage by health insurance carriers for health care services provided to insured Americans, are a serious concern, as another recent survey of 2,000 Americans found that 63 percent have been living paycheck-to-paycheck during the COVID-19 pandemic.[3] Accordingly, a surprise uncovered medical bill could push many American families into financial hardship. A Kaiser Family Foundation poll revealed that 66 percent of adults are concerned that they will incur unexpected medical bills.[4]

Notably, just because a hospital is within a particular insurance network does not necessarily mean that every doctor seeing patients at that hospital is in-network with that same insurance company. There are many reasons why this occurs, which can include specialized services or special patient population needs for which a provider and insurer cannot or will not agree on a reimbursement rate. One study found that between 2010-16, the proportion of emergency room visits to a hospital within an insurance network ultimately resulting in an out-of-network bill increased from 26.3 percent to

1 "No Surprises: Understand Your Rights Against Surprise Medical Bills," Ctrs. for Medicare & Medicaid Servs. (Jan. 3, 2022), *available at* cms.gov/newsroom/fact-sheets/no-surprises-understand-your-rights-against-surprise-medical-bills (unless otherwise specified, all links in this article were last visited on Jan. 11, 2022).

2 David U. Himmelstein, Robert M. Lawless, Deborah Thorne, Pamela Foohey & Steffie Woolhandler, "Medical Bankruptcy: Still Common Despite the Affordable Care Act," *Am. J. of Public Health* (Feb. 6, 2019), *available at* ajph.aphapublications.org/doi/10.2105/AJPH.2018.304901.

3 Jon Berbaum "Survey Reveals Spending Habits During COVID-19," Highland Solutions (Nov. 17, 2020), *available at* highlandsolutions.com/blog/survey-reveals-spending-habits-during-covid-19.

4 Lunna Lopes, Audrey Kearney, Liz Hamel & Mollyann Brodie, "Data Note: Public Worries About and Experience with Surprise Medical Bills," Kaiser Family Found. (Feb. 28, 2020), *available at* kff.org/health-costs/poll-finding/data-note-public-worries-about-and-experience-with-surprise-medical-bills.

42 percent.[5] As such, the average cost that insured patients themselves have had to bear has also risen.

The No Surprises Act provides broadly supported protection to consumers from unanticipated out-of-network health care bills not covered by their insurance carriers. However, the Act and its regulations have also drawn considerable attention due to other potential effects of the legislation and regulations, including concerns over a possible shift in the balance of leverage between providers and insurance payors that could result in fiscal challenges for many providers and ultimately less access to care for consumers.

Legislative History

The No Surprises Act was originally introduced as H.R. 3630[6] on July 9, 2019, by Rep. Frank Pallone, Jr. (D-N.J.), the chairman of the House Energy and Commerce Committee. The bill had bipartisan support, with Reps. Greg Walden (R-Ore.), Ann Wagner (R-Mo.) and Rashida Tlaib (D-Mich.) co-sponsoring the legislation. Although the legislation advanced two days later via voice vote from the House Energy and Commerce Subcommittee on Health for consideration by the full committee, the bill stalled after intense lobbying.[7]

However, legislative momentum continued to build as the 116th Congress, the Trump administration[8] and Presidential candidate Joe Biden[9] took aim at addressing unanticipated medical bills amid the COVID-19 pandemic. As a result, the No Surprises Act was one of many legislative proposals included in the CCA. The CCA, the longest bill ever passed by Congress at 5,593 pages,[10] combined $900 billion in stimulus relief for the pandemic in the U.S. with a $1.4 trillion omnibus spending bill for the 2021 federal fiscal year to prevent a government shutdown.

While the measure was signed into law by President Trump, the Biden administration in 2021 wrote the rules governing how it would be implemented. On July 1, 2021, the Department of Health and Human Services (HHS), Department of Labor and Department of the Treasury (collectively, the "Departments"), along with the Office of Personnel Management (OPM), released an interim final rule with comment period (IFC), titled, "Requirements Related to Surprise Billing; Part I."[11]

Overview of the Law

Prior to the enactment of the No Surprises Act, a patient could be in a medical emergency or see an out-of-network doctor at an in-network facility without having made a conscious choice to go out-of-network, only to then receive an unanticipated out-of-network medical bill. As stated by the USC-Brookings Schaeffer Initiative for Health Policy, "In emergencies, patients can unavoidably end up at an out-of-network facility or being treated by out-of-network physicians. For elective care, patients choose their facility and principal physician, but typically not their anesthesiologist, assistant surgeon, or other ancillary provider; yet these ancillary providers contract with insurers separately from the facilities they practice at (and typically separately from the principal physician)."[12] Accordingly, these types of services would often generate an unanticipated out-of-network bill for the patient that the CCA seeks to address.[13] A policy goal of the legislation was to eliminate patients from being caught in the middle of the negotiation between medical providers and insurers while limiting their out-of-pocket costs to amounts that would have been owed had the provider been within their insurance network.[14] Similar to the administration of the Affordable Care Act, the individual states are tasked in the first instance with administering the No Surprises Act.[15]

Services covered under the No Surprises Act include emergency services, post-emergency stabilization services and non-emergency services incurred at in-network facilities.[16] As a result of the legislation, patients are now more likely to be individually responsible for the cost of emergency services provided by out-of-network providers as if the services were provided by an in-network provider.[17] It also limits patient responsibility for non-emergency services performed by out-of-network providers at in-network facilities as if they were in network, subject to certain exceptions.[18] Accordingly, patients cannot be balance-billed for emergency services or out-of-network non-emergency services at in-network facilities.[19] The financial implications of this on providers, who will now be subject to limitations set by insurers that such providers did not contract with, could be substantial. Of note, ground ambulances, clinics and urgent care centers are medical providers that are not covered by the No Surprises Act.[20] However, air ambulances are covered.[21]

Many states have their own laws to limit unanticipated medical billing.[22] The No Surprises Act therefore works to supplement state billing laws and provide a floor for patient protection rather than replace all related state laws.[23] Accordingly, the No Surprises Act is intended to provide protections and processes that are not already in place at the local level.[24] At present, 33 states have enacted laws addressing balance-billings, but the scopes of those laws vary.[25] As

5 Lisa Rapaport, "Bills from Out-of-Network Doctors Rising at In-Network Hospitals," Reuters (Aug. 12, 2019), *available at* reuters.com/article/us-health-insurance-surprise-billing/bills-from-out-of-network-doctors-rising-at-in-network-hospitals-idUSKCN1V21VS.

6 For the bill's text, visit congress.gov/116/bills/hr3630/BILLS-116hr3630ih.pdf.

7 Rachel Roubein, "Health Groups Backed Dark Money Campaign to Sink 'Surprise' Billing Fix," *Politico* (Sept. 13, 2019).

8 Jacqueline LaPointe, "White House Gives Congress Until Dec. 31 to Ban Surprise Billing," *REV Cycle Intelligence* (Sept. 30, 2020).

9 For a copy of President Biden's health care plan, visit joebiden.com/healthcare.

10 Andrew Taylor, "$900B COVID Relief Bill Passed by Congress, Sent to Trump," Associated Press, (Dec. 22, 2020).

11 "Requirements Related to Surprise Billing; Part I Interim Final Rule with Comment Period," Ctrs. for Medicare & Medicaid Servs. (July 1, 2021).

12 Loren Adler, Matthew Fiedler, Paul B. Ginsburg, Mark Hall, Benedic Ippolito & Erin Trish, "Understanding the No Surprises Act," Brookings (Feb. 4, 2021), *available at* brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/02/04/understanding-the-no-surprises-act.

13 Karen Pollitz, "No Surprises Act Implementation: What to Expect in 2022," Kaiser Family Found. (Dec. 10, 2021), *available at* kff.org/health-reform/issue-brief/no-surprises-act-implementation-what-to-expect-in-2022.

14 "Here's What the New Ban on Surprise Medical Billing Means for You," NPR (Dec. 30, 2021), *available at* npr.org/sections/health-shots/2021/10/14/1045828215/ban-on-surprise-medical-bills.

15 "The No Surprises Act: Implications for States," State Health and Value Strategies (Jan. 12, 2021), *available at* shvs.org/the-no-surprises-act-implications-for-states.

16 *See* Pollitz, *supra* n.13.

17 "Detailed Summary of No Surprises Act," Am. Hosp. Ass'n (Jan. 14, 2021), *available at* aha.org/system/files/media/file/2021/01/detailed-summary-of-no-surprises-act-advisory-1-14-21.pdf.

18 *Id.*

19 *Id.*

20 Alex Rosenberg, "What the No Surprises Act Means for Your Medical Bills," MSN (Jan. 5, 2022), *available at* msn.com/en-us/money/other/what-the-no-surprises-act-means-for-your-medical-bills/ar-AAStzRV.

21 *Id.*

22 "State Balance-Billing Protections," Commonwealth Fund (Feb. 5, 2021), *available at* commonwealthfund.org/publications/maps-and-interactives/2021/feb/state-balance-billing-protections.

23 *See* "No Surprises," *supra* n.1.

24 *Id.*

25 *See* "State Balance-Billing Protections," *supra* n.22.

such, the extent of change occurring as a result of the Jan. 1, 2022, effective date of the No Surprises Act varies by state.[26]

For both providers and patients determining how to appropriately navigate the No Surprises Act, there is an exception to the bar on balance-billing for out-of-network services covered within the legislation if the patient is provided proper notice and gives consent to be billed for out-of-network services.[27] The requirements for notice and consent under the legislation are as follows:

> Written notice and consent must be received within 72 hours of the item or service being delivered or, if the item or service is scheduled within that timeframe, at the time the appointment is made. The notice can be in paper or electronic form (as selected by the patient) and must contain the following information at a minimum: notification that the provider is out-of-network; a good faith estimate of the charges; a list of in-network providers at the facility (if the facility is in-network) to which the patient can be referred; information on any prior authorization or other care management requirements; and a clear statement that consent is optional and the patient can instead opt for an in-network provider. The notice must be available in the 15 most common languages spoken in the provider's area. The HHS Secretary was directed to issue further guidance on these requirements by July 1, 2021, including specifying the form to document patient consent. The legislation requires that this form, at a minimum, includes a space to obtain the patient's signature agreeing that they were provided with appropriate notice, including a cost estimate, as well as the date on which notice was provided and consent obtained. Facilities are generally responsible for maintaining consent documents, including for unaffiliated out-of-network clinicians delivering services in their facility. Records of notice and consent must be retained for seven years after the date on which the item or service was delivered.[28]

However, the notice and consent requirement cannot be used for "emergency services, certain ancillary services, and items or services that are delivered as a result of an unforeseen urgent medical need that arises during a procedure for which notice and consent was received."[29] In hospital settings when informed consent is required, the competency of the patient to make a decision is often a concern.

While there is not a direct correlation between the traditional doctrine of informed consent and the consent requirement within the No Surprises Act, it can be looked at as a guidepost for how consent is reviewed in medical settings. According to the Institute of Clinical Bioethics, the following standards must be met for informed consent to be obtained from a patient: "(1) The Patient should be oriented to time, place, and person ... (2) The patient should understand relevant information ... (3) The risks and benefits of the various options should be clear to the patient ... (4) The consequences of all options — including the refusal of any treatment — should be clearly understood by the patient as well ... [and] (5) The patient should be able to clearly and voluntarily express (verbally or otherwise) his or her preference. If these standards are met, an adult is deemed competent to give valid informed consent."[30]

Present Fault Lines

Prior to the No Surprises Act going into effect, fault lines had arisen over the appropriate methodologies for its implementation and the impact it might have on both medical-service providers and patient access to care if not implemented through carefully balanced regulations consistent with the legislation.[31] Certain medical service provider associations have now filed lawsuits seeking to block aspects of the regulations implementing the law based upon arguments that the regulations, as designed, are contrary to the No Surprises Act itself and are biased toward insurers in a manner that will hurt both providers and patient access to care.[32]

As part of the preparation for the No Surprises Act coming into effect, the Biden administration, through the Departments and OPM, issued a rule on Sept. 30, 2021,[33] the stated intention of which was to detail "a process that will take patients out of the middle of payment disputes, provides a transparent process to settle out-of-network rates between providers and payers, and outlines requirements for health care cost estimates for uninsured (or self-pay) individuals."[34] Much of the debate around the Sept. 30 Rule has been centered around the asserted unfair use of the qualifying payment amount (QPA) as the benchmark for determining the appropriate amount payable by insurers for out-of-network services.[35] "The QPA (qualifying payment amount) is generally the plan or issuer's median contracted rate for the same or similar service in the specific geographic area."[36] Said differently, the QPA is the median *in-network* rate in a specific locale.[37] Vocal challenges to the law and regulations by health care providers to date have largely not been centered around the use of the QPA in determining a patient's responsibility for out-of-network services; however, use of the QPA as a benchmark for the insurer's payment obligation for out-of-network services, as opposed to being considered as a single factor in a multi-factored inquiry, is viewed by health care providers challenging the rule as significantly shifting the balance of leverage in industry-wide negotiations inappropriately to insurers over providers.[38]

26 *See* "No Surprises," *supra* n.1.
27 *See* "Detailed Summary of No Surprises Act," *supra* n.17.
28 *Id.*
29 *Id.*
30 "Competence and Informed Consent," Inst. of Clinical Bioethics (Feb. 9, 2009), *available at* sites.sju.edu/icb/competence-and-informed-consent.
31 "AHA, AMA and Others File Lawsuit Over No Surprises Act Rule that Jeopardizes Access to Care," Am. Hosp. Ass'n (Dec. 9, 2021), *available at* aha.org/news/news/2021-12-09-aha-ama-and-others-file-lawsuit-over-no-surprises-act-rule-jeopardizes-access.
32 *Id.*
33 "Biden-Harris Administration Advances Key Protections Against Surprise Medical Bills, Giving Peace of Mind to Millions of Consumers Plagued by High Costs," Health & Human Servs. (Sept. 30, 2021), *available at* hhs.gov/about/news/2021/09/30/biden-harris-administration-advances-key-protections-against-surprise-medical-bills.html.
34 *Id.*
35 *Am. Med. Assoc., Am. Hosp. Ass'n, et al. v. U.S. Dep't of Health & Human Servs., et al.*, Civil Action No. 1:21-cv-032331, (D.D.C. 2021) at *5.
36 "Requirements Related to Surprise Billing; Part II Interim Final Rule with Comment Period," Ctrs. for Medicare & Medicaid Servs. (Sept. 30, 2021), *available at* cms.gov/newsroom/fact-sheets/requirements-related-surprise-billing-part-ii-interim-final-rule-comment-period.
37 *Id.*
38 Melinda Hatton & Molly Smith, "Blog: Why Hospitals and Physicians Are Filing Suit over No Surprises Act Final Rules that Jeopardize Patient Access to Care," Am. Hosp. Ass'n (Dec. 9, 2021), *available at* aha.org/news/blog/2021-12-09-blog-why-hospitals-and-physicians-are-filing-suit-over-no-surprises-act-final.

Katie Keith, a research faculty member at the Center on Health Insurance Reforms at Georgetown University, opined that insurance premiums may drop as a result of the No Surprises Act, as "the Biden administration appears to 'put a thumb on the scale' [in the Sept. 30 Rule] to discourage settlements at amounts higher than most insurers generally pay for in-network care."[39] In a release put out on Nov. 22, 2021, Health and Human Services Secretary Xavier Bacerra stated that "[t]he Biden-Harris Administration will continue implementing federal regulations from the No Surprises Act to not only protect the patients but also curb rising costs in health care."[40]

Health care provider groups immediately opposed the Sept. 30 Rule characterizing it as a gift to the insurance industry and not reflective of the cost to deliver care in varying circumstances, and warning that it could decrease access to medical care.[41] Various lawsuits have been filed by health care providers to halt the current implementation method of the No Surprises Act, including the case of the *American Medical Association, American Hospital Association, et al. v. U.S. Department of Health and Human Services, et al.*, pending in the U.S. District Court for the District of Columbia. In an *amicus* brief filed by the Federation of American Hospitals, the Association of American Medical Colleges, America's Essential Hospitals, the Catholic Health Associations of the United States and the Children's Hospital Association (collectively, the "Hospital Associations"), it was argued that the regulatory implementation of the No Surprises Act contravenes the legislation as passed by Congress by converting the QPA into "a *de facto* payment benchmark."[42]

The Hospital Associations cite the House Committee press release issued upon the passage of the No Surprises Act stating that with respect to the arbitration process, the neutral arbiter "is required to consider the median in-network rate, information related to the training and experience of the provider, the market share of the parties, previous contracting history between the parties, complexity of the services provided, and any other information submitted by the parties."[43] Accordingly, the Hospital Associations challenge current regulations as having failed to "stay ... within the statutory limits set by Congress" and argue that executive branch agencies do not have the power to rewrite unambiguous terms in legislation to obtain policy goals.[44] As a result of the alleged undue preference for the QPA, the Hospital Associations assert that "[i]f insurers can count on the QPA being the payment amount, they have little incentive to offer anything else during the statutory 'open negotiation' process ... or to negotiate fair in-network contracts with hospitals and physicians that treat complex, high-cost cases."[45] This unintended additional bargaining leverage for insurers will result in fewer in-network contracts, limiting patients' access to specialty and subspecialty care, increasing the volume of out-of-network care, delaying care and ultimately increasing costs due to poorer outcomes.[46]

Emily Carroll, senior legislative attorney for the AMA Advocacy Resource Center, asserts as follows as to the impact that the Sept. 30 Rule has already had on medical providers: "And so they're going to have the choice to sort of accept that median network rate, which is likely much lower than the cost of care, or they're going to be dropped from their networks. And we're already seeing this play out in states like North Carolina, where we had a major payer send letters to a number of providers, essentially saying that as a direct result of this interim final rule, they're cutting rates or dropping them from their networks. This is all happening sort of in the context of independent physical practices, really trying to get back in *[sic]* feet after the pandemic and that financial strain on some of these independent practices really threaten[s] access. So I think we're going to see narrower networks reduce access to care and reduce patient choice."[47] Secretary Becerra has defended the implementation of the Sept. 30 Rule using QPA as the presumptive appropriate out-of-network amount by asserting that the HHS wants an "efficient, transparent and cost-effective" system for resolving disputes between providers and insurers.[48]

Conclusion

While the No Surprises Act is in its infancy, with its recent effectiveness and pending litigation over its implementing regulations, industry professionals will need to actively monitor the regulatory state of affairs and consider optimal business structures and appropriate notices to patients depending on their current business models. In the context of an industry grappling with higher fixed costs due to COVID-19, providers are carefully considering the potential additional effects on the health care marketplace based on where the balance of leverage ultimately lands between insurers and providers after resolution of litigation in the courts addressing the validity of the implementation of the No Surprises Act.[49] These issues are — and will continue to be — particularly acute in the near term for providers, especially those providers that are providing specialty services or are in communities with limited access to health care and are out of network. abi

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39 Julie Appleby, "Surprise-Billing Rule 'Puts a Thumb on the Scale' to Keep Arbitrated Costs in Check," Kaiser Family Found. (Oct. 14, 2021), *available at* khn.org/news/article/surprise-billing-rule-puts-a-thumb-on-the-scale-to-keep-arbitrated-costs-in-check.

40 "New HHS Report Highlights How the No Surprises Act Will Prevent Surprise Medical Bills Faced by Millions of Americans," Dep't of Health & Human Servs. (Nov. 22, 2021), *available at* hhs.gov/about/news/2021/11/22/new-hhs-report-highlights-how-no-surprises-act-will-prevent-surprise-medical-bills-faced-millions-americans.html.

41 *See* Appleby, *supra* n.39.

42 *Am. Med. Assoc., Am. Hosp. Ass'n, et al.*, Civil Action No. 1:21-cv-032331, at *5.

43 *Id.* at *4.

44 *Id.* at *5.

45 *Id.* at *6.

46 *Id.*

47 "What Physicians Need to Know About the No Surprises Act," Am. Med. Ass'n (Dec. 14, 2021), *available at* ama-assn.org/delivering-care/patient-support-advocacy/what-physicians-need-know-about-no-surprises-act.

48 Michael McAuliff, "Becerra Says Surprise Billing Rules Force Doctors Who Overcharge to Accept Fair Prices," Kaiser Family Found. (Nov. 22, 2021), *available at* khn.org/news/article/xavier-becerra-surprise-billing-rules-hhs-report-price-negotiation-arbitration.

49 *See, e.g.*, Lauren Coleman-Lochner, "U.S. Hospitals Pushed to Financial Ruin as Nurses Quit During Pandemic," Bloomberg (Dec. 21, 2021), *available at* bloomberg.com/news/articles/2021-12-21/u-s-hospitals-pushed-to-financial-ruin-as-nurses-quit-en-masse.