# Health Care & Life Sciences

### **CLIENT ALERT**

### The No Surprises Act: A Look at the First Round of Federal Regulations on Surprise Billing

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Earlier today, July 13, 2021, the Biden administration ("Administration") officially published the "Requirements Related to Surprise Billing; Part I"-its first regulatory response to the enactment of the No Surprises Act ("NSA")—as an interim final rule ("IFR") with a request for comments ("First NSA Rule") in the *Federal Register*.<sup>1</sup> Issued by the U.S. Office of Personal Management ("OPM") and the Departments of Health and Human Services ("HHS"), Labor, and the Treasury (collectively, the "Departments"), the First NSA Rule leads the series of regulations the Administration expects to issue to implement the NSA, which goes into effect on January 1, 2022. The Administration initially released the First NSA Rule to the public as a pre-issuance on July 1, 2021, to meet the first regulatory deadline imposed by the NSA. A copy of the official Federal *Register* version of the First NSA Rule can be obtained at the following link: https://www.federalregister.gov/documents/2021/07/13/2021-14379/reguirements-relate d-to-surprise-billing-part-i. Comments are due September 7, 2021.<sup>2</sup>

The bipartisan NSA was signed into law on December 27, 2020, by former President Trump as part of the Consolidated Appropriations Act, 2021. Through the NSA, Congress established a new federal program that includes new federal limitations on patients receiving surprise bills, specifically on when it is appropriate or inappropriate for a nonparticipating provider to bill a patient with commercial insurance coverage above the innetwork patient out-of-pocket amount for covered emergency services provided by that non-participating provider or certain covered nonemergency services provided by that non-participating provider at a participating facility.<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> CMS Fact Sheet on the Requirements Related to Surprise Billing; Part I Interim Final Rule with Comment Period (July 1, 2021). An updated version was released by the Departments on July 6, 2021: Interim Final Rules with Request for Comments on Requirements Related to Surprise Billing; Part I (July 6, 2021). The official Federal Register version was released on July 13, 2021: Interim Final Rules with Request for <u>Comments on Requirements Related to Surprise Billing; Part 1 (July 13, 2021)</u>. <sup>2</sup> Comments may be submitted online or by mail. To submit a comment online, use the following link:

https://www.regulations.gov/commenton/CMS-2021-0117-0001.

<sup>&</sup>lt;sup>3</sup> The First NSA Rule highlights that balance billing will continue "to be permitted, unless prohibited by state law or contract, in circumstances where these interim final rules do not apply, such as for non-emergency items or services provided at facilities that are not included within the definition of health care facility in www.ebglaw.com

The sweeping provisions of the First NSA Rule reiterate the significant impact the NSA will have across the health care industry: on providers, hospitals, laboratories, patients, and health plans and insurers—including group health plans and health insurance issuers offering group or individual health insurance coverage and grandfathered health plans, and carriers in the Federal Employees Health Benefits ("FEHB") Program.

In this Client Alert, we:

- (1) provide a high-level overview of the NSA provisions addressed in the First NSA Rule,
- (2) identify the many issues on which the Administration specifically requests comment within the First NSA Rule, and
- (3) list the NSA provisions that will likely be addressed in future rulemaking and guidance issuances and the expected timing for such issuances.

A summary of the elements of the NSA can be found in the Epstein Becker Green ("EBG") Client Alert titled "<u>The No Surprises Act: Implications for Health Plans, Health Care Facilities, and Health Care Providers</u>," published earlier this year. EBG's June 2021 Client Alert titled "<u>More Surprises on Surprise Billing</u>: <u>Will Federal or State Law Control?</u>" provides an overview of the interaction between state surprise billing laws and the NSA. That Client Alert will be updated to reflect the additional nuances provided by the First NSA Rule.

EBG is closely tracking the NSA and—in addition to summarizing and analyzing each of the forthcoming regulations—will be releasing a series of Client Alerts to provide a deeper analysis of the significant areas addressed in the NSA-related regulations and guidance and the impacts such issuances may have on stakeholders across the health care industry.

Among other topics, EBG plans to issue future Client Alerts or updates that:

- re-examine the nuances regarding the interaction between state surprise billing laws and the NSA,
- analyze aspects of the **QPA calculation**,
- discuss the potential impacts and burdens of the First NSA Rule's notice and disclosure requirements on providers and facilities, and
- assess the implications of the NSA on clinical laboratories.<sup>4</sup>

these interim final rules." <u>Interim Final Rules with Request for Comments on Requirements Related to</u> <u>Surprise Billing; Part 1, page 36877 (July 13, 2021)</u>.

<sup>&</sup>lt;sup>4</sup> Additional topics may include air ambulances and the impact of the First NSA Rule on FEHB plans, among others.

Clients and other interested entities should let us know what other aspects of the NSA's implementation are of concern, and we will consider preparing a related Client Alert.

### I. <u>The NSA Provisions Addressed in the First NSA Rule and Related</u> <u>Guidance</u>

The NSA—which amended the Internal Revenue Code, the Employee Retirement Income Security Act, the Federal Employees Health Benefits Act, and the Public Health Service Act—sets forth various deadlines for the Departments to issue implementing regulations and guidance. Among those deadlines, the NSA required the Departments to issue regulations addressing the "qualified payment amount" ("QPA"), which must be considered by the independent dispute resolution entity in rendering a decision on a dispute under the NSA, and guidance addressing the NSA's notice and consent exception, by July 1, 2021.<sup>5</sup> The First NSA Rule not only addresses the QPA and the notice and consent exception but also provides clarification on several other significant provisions of the NSA. In addition, concurrent with the release of the pre-issuance version of the First NSA Rule, the Departments released a Model Notice<sup>6</sup> for use by group health plans and health insurance issuers, along with several fact sheets for stakeholders.<sup>7</sup>

The following is a series of charts that provide a list of the topics and specific areas addressed in the First NSA Rule and in the guidance documents, consolidated by the products and types of services to which provisions in the First NSA Rule apply.

Торіс	Provisions Addressed in the First NSA Rule
Definitions	<ul> <li>Definitions and the scope of surprise billing protections, including of emergency services; post- stabilization services; non-emergency services performed by nonparticipating providers at participating health care facilities; health care facilities; items and services within the scope of a visit; and air ambulance services</li> </ul>
Determining the Member Cost- Sharing Amount & Payment Amount to Providers and Facilities	<ul> <li>Determining the member cost-sharing amount; out-of-network rate; specified state law; state law interaction with ERISA and examples involving specified state laws; and all-payer model agreements</li> </ul>
Methodology for Calculating the Qualifying Payment Amount	<ul> <li>Methodology for calculating the median contracted rate; contracted rate; including identifying the insurance market; same or similar item or service; provider in the same or similar specialty; facility of the same or similar facility type; geographic regions; and non-fee-for-service contractual arrangements</li> <li>Indexing</li> <li>Special rules for unit-based services – anesthesia services; air ambulance services</li> <li>Cases with insufficient information – definition of sufficient information; eligible databases; new plans and coverage; new service codes</li> <li>Information to be shared about the QPA – definition of sufficient information; eligible databases; new plans and coverage; new service codes</li> <li>Information to be shared about the QPA</li> <li>Audits</li> </ul>
Notice and Consent Exception to Prohibition on Balance Billing	<ul> <li>Standards for notice – authorized representatives; content of notice</li> <li>Standards for consent – language access; exceptions to the availability of notice and consent; retention of certain documents; requirements to notify the plan or issuer</li> </ul>
Provider and Facility Disclosure Requirements Regarding Patient Protections against Balance Billing	<ul> <li>Content of disclosure; methods of disclosure; timing of disclosure to individuals; exceptions; special rule to prevent unnecessary duplication with respect to providers; model notice</li> </ul>

<sup>5</sup> See 29 U.S.C. § 1185e(a)(2); see also 42 U.S.C. § 300gg-132.

<sup>6</sup> Instructions for Group Health Plans and Health Insurance Issuers Model Notice (July 1, 2021).

<sup>7</sup> CMS Fact Sheet on the Requirements Related to Surprise Billing; Part I Interim Final Rule with Comment Period (July 1, 2021); CMS Fact Sheet for Consumers, What You Need to Know about the Biden-Harris Administration's Actions to Prevent Surprise Billing (July 1, 2021); CMS Fact Sheet for Group Health Plans and Health Insurance Issuers (July 1, 2021); HHS News Release, HHS Announces Rule to Protect Consumers from Surprise Medical Bills (July 1, 2021).

<ul> <li>Additional plan and issuer requirements regarding making initial payments or providing a notice of denial</li> <li>Surprise billing complaints regarding group health plans and health insurance issuers</li> <li>Choice of health care professionals</li> <li>Applicability</li> <li>Intent to use enforcement discretion for good faith compliance efforts</li> <li>Conforming changes for FEHB Program; preemption and OPM enforcement; definitions; complaints; jurisdiction of courts; applicability</li> <li>Process for submitting surprise billing complaints regarding health care providers, facilities, and providers of air ambulance services</li> <li>Catastrophic plans</li> </ul>

### II. <u>Areas on Which the Departments Specifically Request Comments in the</u> <u>First NSA Rule</u>

The Departments determined that engaging in full notice and comment rulemaking before putting the regulations into effect would be impracticable and contrary to the public interest, particularly due to the statutory July 1, 2021, deadline for the first round of regulations.<sup>8</sup> Additionally—according to the First NSA Rule—the Departments sought to allow stakeholders sufficient time to prepare to comply with the rules.<sup>9</sup> As such, the Departments released the First NSA Rule in the form of an IFR with a request for comments. The First NSA Rule's provisions will become effective on applicable plans, providers, facilities, and providers of air ambulance services beginning on January 1, 2022. Although the Departments did not include such language, federal regulatory entities issuing IFRs typically stipulate that they will alter the interim rule if warranted by the public comments filed. If an agency decides not to alter an IFR after considering the comments filed, the agency generally will publish a brief final rule in the *Federal Register* confirming that decision.

Additionally, while the First NSA Rule clarifies several aspects of the NSA's requirements, it also raises further questions and seeks comments in notable areas. For example, the Departments seek comments with respect to the information that a plan or issuer must share with a nonparticipating provider or nonparticipating emergency facility, as applicable, when making a determination of a QPA. The First NSA Rule requires plans and issuers to make certain disclosures, either on paper or electronically, when making an initial payment or issuing a notice of denial of payment. Commenters might request additional clarification of how such information should be shared when there is no relationship between the plan or issuer and the non-participating provider and, therefore, likely no HIPAA-compliant electronic connection through which to share the information. Commenters might further seek clarification of whether plans or issuers will be required to conduct some type of credentialing review of the non-participating provider prior to sharing the requested information to ensure, for example, that the person seeking the information is in fact a licensed provider of medical services or items and not a perpetrator of fraud. As detailed in the chart below, the Departments solicit comments in over 40 sections of the preamble of the First NSA Rule, seeking feedback on multiple issues in many of these sections.

<sup>&</sup>lt;sup>8</sup> Interim Final Rules with Request for Comments on Requirements Related to Surprise Billing; Part 1, page 36917 (July 13, 2021).

<sup>&</sup>lt;sup>9</sup>See *id.* at 36918.

The First NSA Rule also contains a section listing regulatory alternatives the Departments considered when developing the regulation.<sup>10</sup> These alternative proposals—which certain stakeholders may prefer to those policy decisions selected by the Departments in the First NSA Rule—can be helpful in fully understanding the Departments' policy considerations and in informing comments to submit in response to the First NSA Rule. Among other topics, the regulatory alternatives section provides an overview of the Departments' considerations in determining the cost-sharing amount, in setting the methodology to calculate the QPA, in defining a "health care facility," in the development of the notice and consent exception, and regarding the applicability date—all of which are key policy determinations. Stakeholders may find these alternatives, such as the determination of the median contracted rate to calculate the QPA, as areas ripe for comment. Additionally, stakeholders may find the section discussing cost estimates for compliance with the regulation, particularly with respect to estimating the costs associated with claims processing and the burdens imposed on nonparticipating providers, to be crucial and should consider commenting if they find that the estimates provided do not adequately reflect or are out of alignment with business realities across the health industry.

The following chart details the many areas in which the First NSA Rule seeks public comment. These comments are due on **September 7, 2021**.

Topic in the IFR	Specific Aspect on Which the Departments Requested Comments	Fed. Reg. Page # <sup>11</sup>
	I. Background	
Surprise Billing and the Need for Greater Consumer Protections	• The First NSA Rule's impact on <b>underserved and minority communities</b> , and how to remove barriers— particularly regarding communication, literacy, language, and cultural differences—so these communities may benefit from the First NSA Rule's consumer protections	36875
	II. Overview of Interim Final Rules – Departments of HHS, Labor, and the Treasury	
Definitions	<ul> <li>The appropriateness and usability of the definitions laid out in the First NSA Rule</li> <li>Whether additional terms should be defined in future rulemaking</li> </ul>	36878
<ul> <li>"Post- Stabilization Services"</li> </ul>	<ul> <li>The definition of "reasonable travel distance" and whether specific standards or examples should be provided regarding what constitutes an unreasonable travel burden for post-stabilization traveling distance, given the transportation barriers faced by underserved and geographically isolated communities</li> <li>The conditions that must be satisfied for post-stabilization services to be excepted from the definition of "emergency services"</li> <li>The guidelines needed—beyond state laws regarding informed consent—to determine whether a stabilized individual is in a condition to receive written notice and provide consent</li> </ul>	36880 - 36882
• "Health Care Facilities"	<ul> <li>If the definition of a "participating emergency facility" should include facilities that have a single case agreement in place with a plan or issuer with respect to a specific individual's care</li> <li>Other facilities to designate as "health care facilities," where surprise bills frequently arise</li> <li>Information to help the Departments determine if urgent care centers or retail clinics—if used in a way similar to independent freestanding emergency departments—should be considered "health care facilities," particularly due to state-level facility definitions</li> </ul>	36882

<sup>&</sup>lt;sup>10</sup> See *id*. at 36930 – 32.

<sup>&</sup>lt;sup>11</sup> Page numbers reference the *Federal Register* version of the IFR. <u>Interim Final Rules with Request for</u> <u>Comments on Requirements Related to Surprise Billing; Part 1 (July 13, 2021)</u>.

Topic in the IFR	Specific Aspect on Which the Departments Requested Comments	Fed. Reg. Page # <sup>11</sup>
• Items and Services within the Scope of a Visit	<ul> <li>Items and services that should be included within the scope of a "visit"</li> </ul>	36882 – 36883
<ul> <li>Cost-Sharing Amount</li> </ul>	<ul> <li>Alternate approaches for calculating the cost-sharing amount for air ambulance services furnished by nonparticipating providers</li> </ul>	36883 – 36884
• Specified State Law	<ul> <li>If health insurance issuers, providers, and/or facilities should have the opportunity to opt-in to state-level surprise billing laws ("specified state law") to determine the payment amount, even when not otherwise subject to such laws</li> <li>The impact of opting-in on underserved and rural communities</li> </ul>	36885 – 36886
<ul> <li>Examples Involving Specified State Laws</li> </ul>	• Approaches to determine the <b>choice of law</b> in circumstances when laws of more than one state apply to a health insurance issuer or provider for a particular item or service	36886 - 36887
Methodology for Calculating the Qualifying Payment Amount	<ul> <li>All aspects of the methodology to determine the QPA</li> <li>Any considerations or factors that are not sufficiently accounted for in the First NSA Rule's QPA methodology</li> <li>Impacts of the methodology on cost sharing, payment amounts, and provider network participation</li> <li>Areas where additional rulemaking or guidance is necessary</li> <li>The impact of large consolidated health care systems on contracted rates</li> <li>The impact of contracted rates on prices and the QPA, and whether adjustments are needed</li> </ul>	36888 – 36889
Contracted Rate	<ul> <li>The definition of a "contract" in situations when plans or issuers rent provider networks or otherwise contract with third parties to manage provider networks</li> </ul>	36889
• Insurance Market	<ul> <li>The definition of "insurance market" for self-insured group health plans</li> <li>If any contractual or other issues may prevent an entity—such as a third-party administrator ("TPA")—from using contracted rates from different self-insured plans it administers to calculate the QPA for a particular self-insured group health plan</li> <li>The ability of self-insured group health plan fiduciaries to monitor the calculation of the QPA by the administering entities for compliance</li> </ul>	36889 - 36890
• Facility of the Same or Similar Facility Type	<ul> <li>If the QPA should be calculated separately or together for hospital emergency departments and independent freestanding emergency departments if plans or issuers vary payment rates based on facility type</li> </ul>	36891 – 36892
<ul> <li>Eligible Databases</li> </ul>	<ul> <li>The standards for ownership and affiliation of databases to avoid conflicts of interest</li> <li>Determining when a database has "sufficient information"</li> <li>The consistency requirements for database selection and preventing abuse in selecting a database</li> </ul>	36895 – 36897
<ul> <li>New Plans and Coverage</li> </ul>	<ul> <li>If new plans and coverage should be permitted to calculate a QPA using median contracted rates during an applicable first sufficient information year</li> </ul>	36897
<ul> <li>New Service Codes</li> </ul>	<ul> <li>If additional rules are needed regarding how plans and issuers should be required to identify a reasonably related service code, and whether the Departments should develop a crosswalk methodology to identify related service codes for each new service code</li> <li>If future rulemaking should specify additional requirements for determining the relativity ratio for items and services billed using a new service code with no Medicare-established payment rate</li> <li>Alternate approaches that could be used to determine the QPA for new service codes</li> </ul>	36897 – 36898
<ul> <li>Information to be Shared about the QPA</li> </ul>	<ul> <li>Disclosure requirements, including what additional information a plan or issuer should be required to share with a provider or facility about the QPA</li> </ul>	36898 – 36899

Topic in the IFR	Specific Aspect on Which the Departments Requested Comments	Fed. Reg. Page # <sup>11</sup>
Additional Plan and Issuer Requirements Regarding Making Initial Payments or Providing a Notice of Denial	<ul> <li>Modifications to HIPAA standard transactions to submit claims to accommodate the submission of several types of information about the claim itself</li> <li>If additional standards are necessary to prevent abusive claims payment practices</li> <li>Setting a minimum payment rate or methodology in future rulemaking, such as setting the amount at: <ul> <li>a specific percentage of the Medicare rate,</li> <li>a specific percentage of the plan or issuer's QPA for the item or service,</li> <li>an amount calculated in the same way the plan or issuer typically calculates payment for the specific item or service to nonparticipating providers or facilities,</li> <li>an amount representing the highest amount that would result from applying two or more of these or other methodologies, or</li> <li>another method</li> </ul> </li> <li>An appropriate specific percentage, if commenters suggest using a percentage of a rate calculated or determined in a specific way</li> <li>If a minimum payment rate should be defined as a commercially reasonable rate based on payments for the same or similar services in a similar area, without requiring any specific methodology</li> <li>The impact of these provisions on underserved and rural communities, and other communities facing a shortage of providers</li> </ul>	36899 – 36902
Surprise Billing Complaints Regarding Group Health Plans and Health Insurance Issuers	<ul> <li>If the complaints process should be restricted to the QPA</li> <li>Information needed to file a complaint and applicable definitions</li> <li>The time period to file complaints</li> <li>Additional information that may be required to process a complaint</li> <li>The timeframe during which a complainant should receive the notification of the outcome of the complaint</li> <li>Ways to ensure consumers are aware of and know how to use the complaint system</li> <li>Solutions to address specific barriers to the complaint process and ensure equitable access to all aspects of the complaint processes for underserved, rural, and minority communities, among others</li> </ul>	36902 – 36903
Applicability	• If there are any other plans with <b>unique benefit designs</b> that should be exempt from all or some of the IFRs	36903 – 36904
	III. Overview of Interim Final Rules – Department of Health and Human Services	
In General	<ul> <li>The impact on nonparticipating providers and facilities—and plans and issuers receiving bills from nonparticipating providers and facilities—of not having information necessary to determine whether services are covered under a patient's plan or coverage</li> </ul>	36904 – 36905
Notice & Consent Exception • Standards for Notice	<ul> <li>Considerations in balancing between permitting a specialist to refuse to treat an individual unless the specialist can balance bill the individual while ensuring the individual is not being pressured into waiving the balance billing protections</li> </ul>	36906
<ul> <li>Authorized Representatives</li> </ul>	The definition of "family member," which HHS will construe broadly	36906
• Timing of Notice	• Whether the <b>three-hour prior notice requirement</b> is a reasonable length of time if it may delay access to urgent care in some situations, and if the requirement may present barriers to providers' and facilities' ability to comply with the notice and consent document requirements	36906 – 36907
• Content of Notice	<ul> <li>Potential challenges nonparticipating emergency facilities may have in coordinating a good faith estimate on behalf of both the facility and providers</li> <li>The methodology to calculate the good faith estimate amount</li> <li>Whether providers and facilities should be required to include information about what the individual's plan or coverage may cover with an estimate of the individual's out-of-pocket costs, or include specific information about applicable prior authorization and care management requirements</li> <li>Barriers or other burdens facing nonparticipating providers or facilities in obtaining specific information about any prior authorization and care management requirements from a plan or issuer</li> <li>The format and content of the referral list to be included in the notice, and challenges providers may have providing this information</li> <li>Any further requirements that should be applied to providers when furnishing this information to the individual</li> </ul>	36907 - 36908

Topic in the IFR	Specific Aspect on Which the Departments Requested Comments	Fed. Reg. Page # <sup>11</sup>
• Standards for Consent	If additional rulemaking or guidance is needed on how an individual can revoke consent	36908 – 36909
• Language Access	<ul> <li>If the First NSA Rule's provisions and protections related to communication, language, and literacy sufficiently address barriers to ensure all individuals can read, understand, and consider their options related to notice and consent</li> <li>Additional or alternate policies HHS may consider to help address and remove communication barriers</li> <li>Proposals to balance consumer friendliness and usability of documents consistent with the First NSA Rule</li> </ul>	36909 – 36910
<ul> <li>Exceptions to the Availability of Notice and Consent</li> </ul>	<ul> <li>Other "ancillary services" that should be ineligible for the notice and consent exception, particularly for ancillary services for which surprise bills are most common</li> <li>Criteria HHS should use to determine if an advanced diagnostic laboratory tests should be excepted from the definition of "ancillary services" and eligible for the notice and consent exception</li> </ul>	36910 – 36911
• Requirements to Notify the Plan or Issuer	<ul> <li>If additional rulemaking regarding the process and timing of a provider's notification to a plan is needed, including the definition of "timely"</li> <li>Efficient processes to convey the notification from provider to plan</li> <li>Barriers and burdens associated with the requirement that providers and facilities provide plans or issuers with a copy of signed written notice and consent documents</li> <li>Recommendations to ensure plans and issuers have the information without imposing an undue burden on providers and facilities</li> </ul>	36911 – 36912
Provider & Facility Disclosure Requirements	<ul> <li>The content of required disclosures, particularly from minorities, underserved communities,</li> </ul>	36912 – 36913
Content of     Disclosure	individuals with limited English proficiency, and those who prefer information in alternative and accessible formats	
• Methods of Disclosure	<ul> <li>If additional regulatory standards are needed to ensure the accessibility of required disclosure information posted on a provider's or facility's public website</li> <li>The disclosure methods, and if additional methods of providing information should be required or permitted</li> <li>If providers without publicly accessible locations could post disclosure information in a location other than a prominent, centralized location</li> </ul>	36913 - 36914
Timing of     Disclosure to     Individuals	<ul> <li>The First NSA Rule's timing requirements for providers and facilities to provide disclosures to participants, beneficiaries, or enrollees, and whether another timing requirement would be more appropriate</li> </ul>	36914
Exceptions	<ul> <li>The First NSA Rule's exceptions to the notice and consent requirements and whether additional exceptions should be considered</li> </ul>	36914 – 36915
Special Rule to Prevent Unnecessary Duplication with Respect to Providers	<ul> <li>The First NSA Rule's "special rule" to streamline the provision of the required disclosures in instances when an individual may receive disclosure notices both from a provider and facility</li> <li>Other circumstances that may warrant a special rule to prevent unnecessary duplication</li> <li>If providers should be required—not just encouraged—to monitor and report if a facility is not in compliance with the First NSA Rule's disclosure requirements</li> </ul>	36915
Surprise Billing Complaints Regarding Health Care Providers, Facilities, and Providers of Air Ambulance Services	<ul> <li>The First NSA Rule's process to receive consumer complaints regarding violations of the balance billing requirements by health care providers, facilities, and providers of air ambulance services</li> </ul>	36915 – 36916

Topic in the IFR	Specific Aspect on Which the Departments Requested Comments	Fed. Reg. Page # <sup>11</sup>
	IV. Overview of Interim Final Rules – Office of Personnel Management	
Conforming Changes for FEHB Program	Additional considerations in applying the First NSA Rule in the context of the FEHB Program	36916
Jurisdiction of Courts	<ul> <li>OPM's amendments to its regulations on court review that specify certain suits for equitable relief under the First NSA Rule must be brought against OPM by December 31 of the third year after the year the disputed services were rendered</li> </ul>	36917
Applicability	<ul> <li>Conforming requirements to apply to FEHB carriers for appropriate implementation in the FEHB Program</li> </ul>	36917
	V. Economic Impact and Paperwork Burden	
Summary of Impacts Benefits	<ul> <li>Policies to identify and remove barriers that may impede minorities and individuals from underserved communities from exercising their rights under the NSA</li> </ul>	36926 - 36927
Costs	• The First NSA Rule's total annual cost estimates for all issuers and TPAs and any additional costs incurred by plans, issuers, providers, and facilities	36927 - 36930
ICRs Regarding Information to be Shared About QPA (45 CFR 149.140(d))	<ul> <li>The First NSA Rule's total annual burden estimates for all issuers and TPAs providing the initial and additional information related to QPA</li> </ul>	36933 - 36935
ICRs Regarding Provider Disclosure on Patient Protections Against Balance Billing (45 CFR 149.430)	<ul> <li>Costs and burdens associated with the provider disclosure requirement of <b>posting required</b> <b>information on a public website</b></li> <li>The number of facilities that will be affected by these requirements and the number of individuals that would be required to receive the required notice</li> </ul>	36940 – 36941

### III. Areas of Future Rulemaking or Guidance for NSA Implementation

The NSA laid out a series of deadlines for the Departments to issue regulations and/or guidance on specific areas. In addition, the NSA authorized the Departments to make certain rules without imposing specific deadlines. Within the First NSA Rule, the Departments also identified additional topics on which they intend to issue regulations, although they noted that such rulemaking might not occur until after January 1, 2022. In the following chart, we list the areas in which the additional regulations and guidance are required or authorized by the NSA—as emphasized by the First NSA Rule—and the expected timeframes for issuance. As highlighted by the First NSA Rule, which was expected to address the QPA, the scope of rulemaking may extend beyond the "topic" required to be addressed by the NSA-specified deadline.

October 1, 2021 (Required by the NSA)	Audit process and regulations on the QPA
No Later than One Year After the Date of Enactment (Dec. 27, 2021) (Required by the NSA)	<ul> <li>Federal Independent Dispute Resolution ("IDR") process for surprise billing (process, batching of items, process to certify IDR entities, method to select the certified IDR entity, and administrative fees due)</li> </ul>
Jan. 1, 2022 (Required by the NSA)	<ul> <li>Patient-provider dispute resolution process (selection of entity to make the determination, the administrative fee to participate in the patient-provider dispute resolution process, and the process to certify entities)</li> <li>Guidance regarding the standardized reporting format for the State All Payer Claims Databases</li> </ul>
After Jan. 1, 2021 (Specified in the First NSA Rule) <sup>12</sup>	<ul> <li>Transparency in plan and insurance identification cards, continuity of care, accuracy of provider network directories, and the prohibition on gag clauses applicable on plans after Jan. 1, 2021</li> <li>Pharmacy benefit and drug cost reporting required by Dec. 27, 2021</li> </ul>
<b>No Deadline Specified</b> (Authorized or Required by the NSA or Specified in the First NSA Rule)	<ul> <li>Modification of IDR timing requirements of specified items or services (with low utilization or significant variation in cost)</li> <li>The form and manner in which plans, issuers, and providers of air ambulance services would report information regarding air ambulance services</li> <li>Determining the interest rate for repayment when providers unknowingly overbilled</li> <li>Price comparison tools</li> <li>Patient protections through transparency</li> <li>Requirements on health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to disclose and report information regarding direct or indirect</li> </ul>
	<ul> <li>compensation provided to agents and brokers</li> <li>HHS enforcement of requirements on issuers, non-federal governmental group health plans, providers, facilities, and providers of air ambulance services</li> </ul>
No Deadline Specified, but Partially Addressed by the First NSA Rule (Authorized or Required by the NSA)	<ul> <li>Expectations related to good faith compliance with the NSA provisions</li> <li>Items and services provided by specialty practitioners to be considered "ancillary services"</li> <li>A list of advanced diagnostic laboratory tests that will not be considered an ancillary service</li> <li>Facilities that may be considered participating facilities</li> <li>The items and services included in a "visit" to which surprise billing protections apply</li> <li>A process to receive consumer complaints</li> </ul>

### IV. Looking Forward

The NSA requires the Departments to finalize the next round of implementing regulations by October 1, 2021. This First NSA Rule serves as an indication of how the second piece of the rulemaking process may occur. It also will serve to show whether and to what extent stakeholder comments may shape implementation of the NSA and the impact providers, plans, and others may experience as the NSA is implemented.

All stakeholders should take the time to review the First NSA Rule and take advantage of this opportunity to provide comments to the Departments so that the implementation of the NSA can effectively achieve its policy goals for the health care industry. Clients and other interested entities should let us know what other aspects of the NSA's implementation are of concern and we will consider preparing a related Client Alert.

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<sup>&</sup>lt;sup>12</sup> The First NSA Rule states that rulemaking might not occur until after January 1, 2022, but that the Departments will allow a grace period and expect plans and issuers to "implement the requirements using a good faith, reasonable interpretation of the statute." *See id* at 36876.

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