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CLIENT ALERT

The No Surprises Act: New and Surprising Challenges for Clinical Laboratories

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On July 13, 2021, the U.S. Departments of Health and Human Services, Labor, and the Treasury, and the Office of Personnel Management (collectively, "Departments") published their highly anticipated interim final rule ("First NSA Rule") fleshing out portions of the No Surprises Act ("NSA"), which was enacted at the end of 2020.[1] Congress passed the NSA to protect patients from receiving surprise medical bills arising from covered treatment rendered by nonparticipating providers that the patients did not have the opportunity to choose. Specifically, the NSA applies primarily to surprise bills patients receive from nonparticipating providers of emergency services and from nonparticipating providers—like consulting specialists, radiology departments, and clinical laboratories—that provide services to a patient while receiving care for non-emergency services at a participating facility, such as a hospital. The sweeping provisions of the NSA will levelize patient cost-sharing obligations between participating and nonparticipating providers in the foregoing care settings and will prohibit nonparticipating providers from balance billing patients for a cost-sharing amount higher than they would be charged by a participating provider or facility.

This Client Alert focuses on the unique operational and billing impacts clinical laboratories face under the NSA, the implications of which far surpass hurdles laboratories currently face under most state law surprise billing frameworks. Laboratory providers' early understanding of the potential implications of the NSA and First NSA Rule is crucial both for submitting comments to the Departments during continued NSA rule development and refinement and for timely complying with the NSA and related rules, which go into effect on **January 1, 2022.** The First NSA Rule expressly seeks comments on a significant number of its terms, including provisions critical to the laboratory industry. Comments to the First NSA Rule are due **September 7, 2021**.

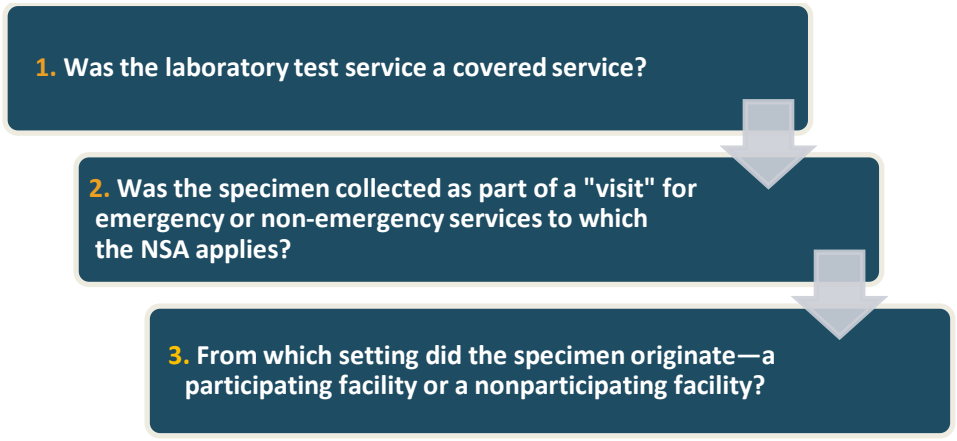
An overview of the elements of the NSA can be found in the Epstein Becker Green ("EBG") Client Alert titled "The No Surprises Act: Implications for Health Plans, Health

[1] Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36872 (July 13, 2021), https://www.federalregister.gov/documents/2021/07/13/2021-14379/requirements-related-to-surprise-billing-part-i.

Care Facilities, and Health Care Providers," an overview of the First NSA Rule is available in the Client Alert titled "The No Surprises Act: A Look at the First Round of Federal Regulations on Surprise Billing," and an analysis of state preemption issues is provided in the Client Alert titled "More Surprises on Surprise Billing: Will Federal or State Law Control?," which will be updated soon to reflect the First NSA Rule.

SOLVING THE THRESHOLD ISSUES REGARDING APPLICABILITY OF THE NSA TO LAB TESTING

As a threshold matter, in order to determine whether a nonparticipating laboratory may balance bill a covered patient, the nonparticipating laboratory must determine whether the services trigger the protections under the NSA. There are three threshold questions nonparticipating laboratories must consider:



As indicated by the questions above, a key obstacle laboratories will face when implementing the NSA is uncertainty about (i) whether their services are covered by the patient's plan or coverage, (ii) whether the test was ancillary to the provision of emergency or non-emergency services, and (iii) whether the facility at which the patient was receiving care was in or out of network for the patient. Therefore, laboratories will need to obtain and assess information they do not regularly receive about the care setting in which a test is ordered; this will significantly limit the ability of laboratories to immediately comply with the NSA's requirements. For example, independent clinical laboratories generally do not receive any information from ordering clinicians that would allow them to determine whether a requested test originated from emergency services furnished by a nonparticipating facility or from non-emergency services in a participating facility, especially if the laboratory provider is out of network relative to the patient. As a result, laboratories will be required to overcome significant information gaps to comply with the NSA, as it currently stands with the First NSA Rule.

1. Was the laboratory test service a covered service?

For nonparticipating laboratory providers, the NSA's balance billing protections would apply only to services delivered by the nonparticipating laboratory for which there is some level of coverage by a patient's health plan. For example, if a test ordered by a participating physician is performed by a nonparticipating laboratory and such test is

either not subject to reimbursement or excluded from the patient's coverage, then the NSA's balance billing prohibitions would not apply because the test would not be considered an item or service for which any benefits are provided or covered by the group health plan or health insurance issuer.[2] While this framework benefits laboratories performing tests not covered by any plans, laboratories may not be aware of current coverage parameters of tests, particularly for newer tests for which coverage might be evolving. As such, laboratories may want to submit comments to the Departments explaining that they typically are not aware of coverage parameters for tests with different payors.

2. *Was the specimen collected as part of a "visit" for emergency or non-emergency services to which the NSA applies?*

The next threshold question for laboratories is whether the test originated from (i) emergency or certain post-stabilization services by a nonparticipating provider at a hospital emergency department or freestanding emergency department or (ii) non-emergency services furnished in a participating facility. In either circumstance, the laboratory would be subject to the NSA's balance billing prohibitions.

Covered Laboratory Services Furnished During a "Visit" for Emergency Services:	• For covered laboratory services performed on a specimen collected during a covered patient's "visit" to receive emergency services at a hospital or emergency department for an emergency medical condition, nonparticipating laboratory providers may not bill covered patients for covered laboratory services above the cost-sharing requirement specified under the NSA and, thus, cannot balance bill the covered patient.
Covered Laboratory Services Furnished When a Patient Receives Non-Emergency Services at a Participating Facility:	• For covered laboratory services performed on a specimen collected during a covered patient's "visit" at a participating facility for covered services, other than services considered "emergency services" defined under the NSA, nonparticipating laboratory providers may not bill covered patients for covered laboratory services above the cost-sharing amount determined under the NSA and, thus, cannot balance bill the covered patient for the covered laboratory services.

Obtaining information required to determine whether either situation applies will pose significant hurdles for laboratories.[3] In most instances, when an independent clinical laboratory receives a specimen for testing from a hospital client, a laboratory is not aware whether a test was ordered in the context of emergency or non-emergency care as contemplated by the NSA. Indeed, typical test requisitioning practice generally does not give labs the information they would need to determine, or distinguish between, the

[2] The NSA applies to 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 Program.

[3] *See* 42 U.S.C. §§ 300gg-131, 132.

specific care context in which a test was ordered, particularly when the test originated from a hospital that may provide different types and levels of care. Understanding the care context of the order will be critical for NSA compliance; it determines how much the laboratory can bill the patient. When a laboratory test is ancillary to an emergency service, the laboratory cannot bill the patient more than the patient's in-network cost-sharing amount regardless of whether the emergency facility or provider that treated the patient is participating or nonparticipating with respect to the patient's coverage. By contrast, when a test is ancillary to a non-emergency service, whether a laboratory can balance bill a patient, and for how much, is a function of whether the facility is in or out of network for the covered patient.

What is clear, however, is that the specimen must have been collected during a "visit." The NSA defines a "visit," with respect to items and services furnished at a health care facility, to include equipment and devices, telemedicine services, imaging services, laboratory services, preoperative and postoperative services, and other items and services specified by the U.S. Department of Health and Human Services ("HHS").[4] The First NSA Rule emphasizes a notable component of the definition—that a "visit" to a participating health facility includes such ancillary services "whether or not the provider furnishing such items or services is at the facility."[5]

This language of the NSA and the First NSA Rule indicates that laboratory tests are subject to the NSA when the patient specimen is collected in conjunction with a "visit" to a "participating health facility" for emergency or non-emergency services and then analyzed on or off site by a separately billing nonparticipating laboratory. The definition of "visit" also strongly suggests that laboratory testing performed on site at a hospital or other facility would be subject to the NSA if the on-site lab maintains its own independent identity (licensure and corporate identity separate from the hospital) and is nonparticipating with the patient. By contrast, follow-up laboratory testing based on an order from when a physician caring for a patient in conjunction with a visit to a participating health facility for emergency or non-emergency services, but for which the specimen was collected later at a nonparticipating laboratory or one of its patient service centers, would fall outside the balance billing protections of the NSA and the First NSA Rule. In other words, totally "off campus" testing—particularly any that is chronologically distinct from the patient "visit" or service—would live outside the protections of the NSA and the First NSA Rule. Laboratory services provided in such circumstances and settings would enable the patient to choose their laboratory services provider, and, thus, the patient would not be surprised by a bill for more than the in-patient cost-sharing amount from the individual's selected out-of-network laboratory provider.

3. From which setting did the specimen originate—a participating facility or a nonparticipating facility?

In addition to understanding whether the test was ordered in the emergency or non-emergency care context, an independent or reference laboratory will likely have difficulty determining whether a facility from which a specimen or order originated for non-

[4] 42 U.S.C. § 300gg-111.
[5] 42 U.S.C. § 300gg-111; 86 Fed. Reg. at 36960 (to be codified at 29 C.F.R. § 2590.716-3).

emergent laboratory services is a participating facility or nonparticipating facility relative to a covered patient's plan or coverage. Laboratories' inability to distinguish between such participating and nonparticipating facilities will slow or prevent lawful balance billing as allowed by the NSA. At present, laboratories have no efficient process to make a determination of whether a patient for whom the lab processed a specimen was at a participating facility under the patient's coverage when the test was ordered and the specimen obtained.

Further complicating matters, urgent care centers present a special problem that spans the two foregoing challenges—determining whether the test ordered and specimen obtained was part of emergency care or non-emergency care at a participating facility. State licensing laws will determine whether an "urgent care center" might be considered a facility to which the NSA's balance billing rules applies. If the urgent care center from which a test originates and a specimen is obtained is authorized by the law of the state in which it is located to provide emergency services, then care provided there, and the associated laboratory services provided, may trigger the NSA if the care otherwise meets the definition of an "emergency service" under the First NSA Rule. If, by contrast, the urgent care center is in a state that does not legally authorize such centers to provide emergency care, then laboratory tests on a specimen originating from a visit to the center fall outside the scope of the NSA and the First NSA Rule's protections. Accordingly, laboratories will need an in-depth understanding of the state licensure and regulatory status of any urgent care centers from which they receive test orders/specimens. Notably, the Departments specifically set forth in the First NSA Rule that they are seeking comments on the extent to which urgent care centers are subject to the purview of the NSA.

COMMENTING TO EXPAND APPLICATION OF THE NOTICE-AND-CONSENT EXCEPTION FOR ADVANCED DIAGNOSTIC LABORATORY TESTS

> ***"HHS seeks comment on what criteria HHS should consider in determining whether an advanced diagnostic laboratory test should be excepted from the definition of ancillary services, and on any specific advanced diagnostic laboratory tests that should be considered to be made eligible for the notice and consent exception."***

In addition to the informational gaps laboratories will face when attempting to implement the NSA, the NSA largely bars nonparticipating laboratory providers from using the notice-and-consent exception to its balance billing prohibition, which would typically allow certain nonparticipating providers to balance bill patients upon the satisfaction of certain notice-and-consent requirements. Although the notice-and-consent exception enables many other types of nonparticipating providers to balance bill patients, the First NSA Rule

highlights that "ancillary services"—defined[6] to include "laboratory testing"—are not eligible for the notice-and-consent exception[7] and that "the prohibition on balance billing and the in-network cost-sharing requirements, as described in these interim final rules, always apply with respect to those items or services."[8]

The NSA's approach to the notice-and-consent exception for ancillary services is a significant departure from the approach taken by several states that have comprehensive surprise billing laws. Such state laws do not typically exclude certain nonparticipating providers from using the state's applicable notice-and-consent exception. For example, Texas specifically includes procedures for nonparticipating laboratory providers to use when providing services ancillary to services covered by Texas' surprise billing law.[9] As the Departments emphasize in the preamble to the First NSA Rule, the NSA "creat[es] a floor regarding individuals' ability to waive balance billing protections." Accordingly, the NSA's exclusion of ancillary services from the eligibility of the notice-and-consent exception would preempt state laws—such as Texas' surprise billing law—that would otherwise permit nonparticipating laboratory providers to balance bill with consent.[10]

The one category of tests for which laboratories may invoke the notice-and-consent exception to the NSA is for advanced diagnostic laboratory tests ("ADLTs"). The NSA states that HHS "through rulemaking [may] establish a list (and update such list periodically) of [ADLTs], which shall not be included as an ancillary service[.]"[11] In other words, once designated as an ADLT, a test would no longer be deemed an ancillary service and, thus, would be eligible for balance billing upon the provider's satisfaction of the NSA's notice-and-consent exception requirements. The First NSA Rule does not define ADLTs and expressly seeks comments and suggests the likelihood of further rulemaking regarding the criteria for what constitutes an ADLT. The door is, therefore, open for labs to broaden the contours of the notice-and-consent exception.

Notably, the invitation for comments suggests that the criteria for what constitutes an ADLT may be different from, and broader than, the criteria used to establish an ADLT under the Protecting Access to Medicare Act ("PAMA"), which has yielded a list of only 10 ADLTs.[12] Assuming a broader array of tests could be designated as ADLTs under the NSA than under PAMA, laboratories would still be faced with the challenge of complying with the notice-and-consent exception provisions of the First NSA Rule, which require the

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[6] Ancillary services, with respect to a participating health facility, include items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether or not provided by a physician or non-physician practitioner, and items and services provided by assistant surgeons, hospitalists, and intensivists; diagnostic services (including radiology and laboratory services); items and services provided by such other specialty practitioners as specified by HHS through rulemaking; and items and services provided by a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility. 42 U.S.C. § 300gg-132.
[7] 86 Fed. Reg. at 36982 (to be codified at 45 C.F.R. §149.420(b)(1)(iii)).
[8] 42 U.S.C. § 300gg-132(b)(2).
[9] Tex. Ins. Code §§ 1551.230(d), 1575.173(d), 1579.111(d), 1271.158(d), & 1301.165(d).
[10] 86 Fed. Reg. at 36931.
[11] 42 U.S.C. § 300gg-132.
[12] 42 USC § 1395m-1(d)(5); CMS, Advanced Diagnostic Laboratory Tests Under the Medicare CLFS (June 15, 2021), https://www.cms.gov/files/document/advanced-diagnostic-laboratory-tests-under-medicare-clfs.pdf.

laboratory or the facility at which the test is ordered and specimen collected to, among other things, provide a good faith estimate of the out-of-pocket expense to the patient in advance of performing the subject test. The daunting task of reasonably calculating a good faith estimate of the amount for a particular test on a plan-by-plan and facility-by-facility basis seems unfathomable, especially for the facility at which the test is offered.

Notwithstanding the foregoing challenges, growing a list of ADLTs subject to the notice-and-consent exception is one of the few areas in which laboratories appear to be able to share the application of the First NSA Rule.

WHAT LABS NEED: INFORMATION SHARING RULES

As noted above, most of the compliance challenges laboratories will face when implementing the NSA will stem from having insufficient information to determine whether the NSA's balance billing provisions apply, including:

- Whether the laboratory testing was ordered as part of an emergency or non-emergency service;
- Whether the non-emergency laboratory testing was ordered at a participating or nonparticipating facility as part of a "visit";
- Whether the test was ordered at an urgent care center that is licensed to offer emergency services, and, if so, whether it was part of a permissible emergency service; and
- What the patient's in-network financial responsibility would be for any given test performed at an in-network facility.

Further rulemaking from the Departments aimed to help consolidate, deliver, and/or make information available to laboratories will be critical for laboratories' successful implementation of the NSA. Without this information, laboratories, especially independent and reference labs, will be unable to fully assess their patient billing rights or plan reimbursement rights under the NSA.

LOOKING FORWARD

Clinical laboratories will be uniquely impacted by the NSA and the First NSA Rule. While an early understanding of the First NSA Rule will provide a road map for proactive compliance with the NSA and the First NSA Rule—set to go into effect in just over six months—successful implementation will require significant enhancement to billing and communications systems among laboratories, providers, and insurers.

Regardless of future rulemaking or modification—which would be unlikely to resolve entirely the obstacles laboratories will face—laboratories must forge ahead with the difficult work of building new information collecting systems to assist with NSA compliance, including by seeking information about the care setting in which a test is ordered, on digital and hard copy laboratory requisition forms.

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. Previous Client Alerts addressing the NSA include the following:

- "The No Surprises Act: Implications for Health Plans, Health Care Facilities, and Health Care Providers" – January 19, 2021
- "More Surprises on Surprise Billing: Will Federal or State Law Control?" – June 30, 2021 (Update pending)
- "The No Surprises Act: A Look at the First Round of Federal Regulations on Surprise Billing" – July 13, 2021

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