Frequently Asked Questions (FAQs) about Consolidated Appropriations Act, 2021 Implementation – Applicability, Notice and Consent:

Set out below are Frequently Asked Questions (FAQs) regarding implementation of Title I (the No Surprises Act (NSA)) of Division BB of the Consolidated Appropriations Act, 2021 (CAA 2021) and implementing regulations published in the Federal Register on July 13, 2021 and October 7, 2021 as part of interim final rules with comment period, entitled "Requirements Related to Surprise Billing; Part I" and "Requirements Related to Surprise Billing; Part II," respectively.

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Applicability:

Q1: The No Surprises Act includes a number of requirements for providers. To which types of providers do the requirements apply?

A: The No Surprises Act's prohibitions on billing participants, beneficiaries, and enrollees for more than their applicable cost sharing amounts (otherwise known as balance billing) apply to nonparticipating providers and nonparticipating emergency facilities furnishing emergency services, as well as to nonparticipating providers furnishing certain nonemergency services in connection with an individual's visit to certain participating facilities, and to nonparticipating providers of air ambulance services.

However, some providers may not practice in a setting or manner that triggers certain requirements of the No Surprises Act related to balance billing. For example, a provider (excluding air ambulance providers) that never furnishes services in connection with an individual's visit to any of certain types of health care facilities¹ or emergency facilities,² would not furnish items or services that fall within the balance billing prohibitions and cost-sharing protections of 45 CFR §§ 149.410 or 149.420, and related disclosure requirements at 45 CFR § 149.430. The table below includes a summary of the No Surprises Act requirements related to balance billing and cost sharing, and their applicability to providers and facilities.

¹ "Health care facility," with respect to a group health plan or group or individual health insurance coverage, in the context of non-emergency services, means each of the following: 1) hospital (as defined in section 1861(e) of the Social Security Act); 2) a hospital outpatient department; 3) a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and 4) an ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

² "Emergency facility," means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 149.110(c)(2)(ii) are included as emergency services).

No Surprises Act protections apply broadly to providers, facilities, and providers of air ambulance services.³ Providers, facilities (including facilities beyond those defined in 45 CFR § 149.30, for the purposes of the balance billing rules related to certain non-emergency services), and providers of air ambulance services must provide a good faith estimate of expected charges for scheduled items or services, or upon request, to uninsured (or self-pay) individuals as required by 45 CFR § 149.610, regardless of the clinical setting in which they furnish care. Similarly, all providers, facilities, and providers of air ambulance services are subject to the continuity-of-care and provider directory requirements in the No Surprises Act, as applicable.⁴

No Surprises Act's Prohibitions on Balancing Billing and Cost-Sharing Protections: Applicability to Providers and Facilities by Category of Service

<u>Note</u>: These requirements apply only with respect to participants, beneficiaries, and enrollees in group health plans, and group and individual health insurance coverage.

Requirement	Applicability to Providers by Category of Service
Prohibition on balance billing, and cost-sharing limitations, in cases of emergency services (45 CFR § 149.410)	Nonparticipating providers and nonparticipating emergency facilities must comply with restrictions on balance billing and limitations on cost sharing set forth at 45 CFR § 149.410 when furnishing emergency services for an emergency medical condition with respect to a visit to: (1) an emergency department of a hospital; or (2) an independent freestanding emergency department.
	Note that emergency services include covered items or services required to stabilize the individual and, unless certain conditions are met, post-stabilization items and services (regardless of the department of the hospital in which such items or services are furnished) that are furnished with respect to a visit to an emergency department for emergency services.
Prohibition on balance billing, and cost-sharing limitations, for non- emergency services (45 CFR § 149.420)	 Nonparticipating providers must comply with restrictions on balance billing and limitations on cost sharing set forth at 45 CFR § 149.420 when furnishing non-emergency items or services as part of an individual's visit* to one of the following types of health care facilities, as defined at 45 CFR § 149.30, so long as the facility is a participating facility in the individual's health plan: A hospital (as defined in Section 1861(e) of the Social Security Act); A critical access hospital (as defined in Section 1861(mm)(1) of the Social Security Act); or

³ "Health care facility" under 45 CFR 149.610(a)(2)(vii) "means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is a pproved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing." "Health care provider" under § 149.610(a)(2)(vii) "means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, including a provider of air ambulance services."

⁴ For more information about these requirements, see, FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021, Implementation Part 49, <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf</u> and https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

	• An ambulatory surgical center (as defined in Section 1833(i)(1)(A) of the Social Security Act).
	The No Surprises Act does not prohibit nonparticipating providers from balance billing or charging cost sharing in excess of applicable amounts for non- emergency services furnished in connection with visits to care settings that are not one of the above listed facilities. For example, an individual's visit to an out- of-network physician's private practice office would not trigger the prohibition on balance billing or prevent charges for cost sharing in excess of applicable amounts.
	The No Surprises Act also does not prohibit nonparticipating providers from balance billing or charging cost sharing in excess of applicable amounts for non- emergency services furnished in connection with an individual's non-emergency visit to a hospital, hospital outpatient department, critical access hospital, or ambulatory surgical center when the health care facility neither participates in the individual's health plan (i.e., is an out-of-network facility) nor has a single case agreement in place with the plan with respect to the individual.
Disclosure requirements regarding protections against balance billing and out-of- network cost sharing (45 CFR § 149.430)	Providers and facilities must comply with certain disclosure requirements specified at 45 CFR § 149.430. This requirement only applies to providers if, as part of their practice, they furnish items or services in connection with individual visits* at one of the following types of facilities:
	 Emergency department of a hospital or independent freestanding emergency department Hospitals (as defined in Section 1861(e) of the Social Security Act); Hospital outpatient departments; Critical access hospitals (as defined in Section 1861(mm)(1) of the
	 Critical access hospitals (as defined in Section 1801(1111)(1) of the Social Security Act); or Ambulatory surgical centers (as defined in Section 1833(i)(1)(A) of the Social Security Act).
Prohibition on balance billing, and cost-sharing limitations, in cases of air ambulance services (45 CFR § 149.440)	Nonparticipating air ambulance services providers who furnish air ambulance services for an individual enrolled in a group health plan or group or individual health insurance coverage offered by a health insurance issuer that provides or covers benefits for such air ambulance services, must comply with restrictions on balance billing and limitations on cost sharing for air ambulance services set forth in 45 CFR § 149.440. This requirement prohibits nonparticipating air ambulance services providers from billing an individual for an amount greater than the applicable cost-sharing amount for air ambulance services (for which benefits are available under the individual's plan or coverage).

* Furnished items or services provided in connection with an individual's visit to a participating health care facility may include items and services that are not physically performed within the health care facility (e.g., offsite laboratory services and telehealth services).

Q2: Do any of the balance billing protections of the No Surprises Act apply when serving individuals covered by Medicare Advantage or Medicaid Managed Care plans?

A: No. The balance billing protections of the No Surprises Act requirements do not apply to providers or facilities in connection with furnishing items or services to beneficiaries or enrollees in federal programs such as Medicare (including Medicare Advantage), Medicaid (including Medicaid managed care plans), Veterans Affairs Health Care, the Indian Health Service, or TRICARE. These programs have other protections in place to address high medical bills.

Notice and Consent

In limited circumstances, nonparticipating providers and nonparticipating emergency facilities are permitted to hold participants, beneficiaries, and enrollees liable for more than the applicable cost-sharing amount if they provide notice to the individual regarding their protections against surprise bills and obtain the individual's consent to waive those protections. Nonparticipating providers and nonparticipating emergency facilities must provide such notice and consent in accordance with HHS regulations. The following questions cover some of the conditions, exceptions, and prohibitions for the notice and consent requirements.

Q3: When are providers and facilities prohibited from using the notice and consent exception to obtain voluntary consent from an individual to waive the balance billing and cost-sharing protections of the No Surprises Act?

A: Without exception, the No Surprises Act prohibits nonparticipating providers and facilities from balance billing and charging more than applicable cost sharing for the following items and services, to the extent they are covered under the terms of a group health plan or group or individual health insurance coverage. As such, providers and facilities should not attempt to provide notice and obtain signed consent to balance bill or charge more than the applicable cost sharing for these items and services.

- Emergency services, as defined at 45 CFR § 149.110(c)(2) (other than certain post-stabilization items and services⁵ that would otherwise be included in the definition of emergency services at 45 CFR 149.110(c)(2)(ii));
- Air-ambulance services, as defined at 45 CFR § 149.30;
- Non-emergency ancillary services provided by a nonparticipating provider in connection with an individual's visit to a participating health care facility, as defined at 45 CFR § 149.420(b)(1) as⁶:
 - Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, provided by either a physician or non-physician practitioner;
 - Items and services provided by assistant surgeons, hospitalists, and intensivists;
 - Diagnostic services, including radiology and laboratory services; and
 - Items and services provided by a nonparticipating provider when there is no participating provider who can provide the item or service at the participating health care facility.

⁶ The statute authorizes the U.S. Department of Health and Human Services (HHS) to expand the definition of ancillary services to include items and services provided by other types of providers. As of the date of these FAQs, HHS has not issued regulations to expand the definition of ancillary services.

⁵ Post-stabilization items and services are items and services for which benefits are provided or covered under the plan or coverage; and that are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which emergency services provided prior to stabilization are furnished.

• Items or services furnished due to unforeseen urgent medical needs in the course of delivering out-ofnetwork post-stabilization or non-emergency services, regardless of whether the nonparticipating provider satisfied the notice and consent criteria as defined at 45 CFR § 149.420.

Q4: Is a nonparticipating provider or emergency facility required to provide notice and seek the individual's written consent in order to waive balance billing and cost-sharing protections of the No Surprises Act?

A: Yes. However, if a nonparticipating provider or facility does not provide notice and obtain written consent in accordance with the applicable regulations, then the nonparticipating provider or facility must not balance bill or hold the participant, beneficiary, or enrollee liable for an amount exceeding the applicable cost-sharing amount. Note, however, in situations in which use of the notice and consent exception process is permitted, there is no requirement that nonparticipating providers and emergency facilities use the notice and consent exception process. In those situations, should the provider or facility is prohibited from balance billing the individual and from charging more than the applicable cost-sharing amount.

Q5: If a nonparticipating provider is furnishing services at a participating health care facility or emergency facility and wishes to provide notice and obtain written consent from an individual to waive balance billing and cost-sharing protections for non-emergency services or post-stabilization services, which entity, the provider or facility, is responsible for providing notice and obtaining written consent from the individual?

A: Under the No Surprises Act and its implementing regulations, in scenarios in which use of notice and consent is permitted, either the nonparticipating provider or the facility, acting on behalf of the provider, may provide notice and obtain written consent from the individual (or authorized representative) to waive the balance billing and cost-sharing protections.

The requirements for retention of notice and consent documents vary slightly depending on the entity that obtains written consent. As outlined in 45 CFR § 149.410(d) and § 149.420(h), if a participating health care facility obtains written consent on behalf of the provider, the health care facility must retain the written notice and consent for at least a 7-year period. Alternatively, if a nonparticipating provider obtains written consent, where the facility does not otherwise obtain written consent on behalf of the provider, the provider may either coordinate with the facility to have the facility retain the written notice and consent for a 7-year period.

Q6: Can nonparticipating providers and facilities rely on oral consent from individuals to waive the balance billing and cost-sharing protections under the No Surprises Act?

A: No. Nonparticipating providers and facilities are not allowed to rely on oral consent from individuals to waive their balance billing and cost-sharing protections under the No Surprises Act. In order to obtain consent from an individual to waive these protections, in situations where the No Surprises Act and its implementing regulations permit a provider or facility to seek such consent, a provider or facility must provide the individual (or an authorized representative) with the required notice in writing, either in paper or electronic form, obtain written signed consent from the individual (or an authorized representative), and provide a copy of the signed notice and consent form to the individual, either in-person, or through mail or via email, based on the individual's preference. An individual cannot give consent over the phone.

HHS has published a standard <u>notice and consent form</u> that providers and facilities are required to use when obtaining written signed consent from an individual to waive the balance billing and cost-sharing protections of the No Surprises Act.

Q7: Can nonparticipating providers or facilities seek consent from an individual to waive the balance billing and cost-sharing protections at the time care is to be furnished?

A: No. Providers and facilities cannot seek consent from an individual (or their authorized representative) to waive balance billing and cost-sharing protections at the time care is to be furnished. As required by 45 CFR § 149.420(c)(1)(iii), if services are scheduled at least 72 hours in advance of the date when items or services will be furnished, then the required written notice and consent form must be provided to the individual at least 72 hours in advance of the date when items or services will be furnished. If services are scheduled less than 72 hours in advance of the date when items or services will be furnished, then the notice and consent form must be provided to the notice and consent form must be provided on the date the appointment is scheduled, no later than 3 hours prior to when the items or services will be furnished.