American Hospital Association™

Advancing Health in America

No Surprises Act
Implementation Handbook
As of: March. 25, 2022

The No Surprises Act established new patient protections against balance billing in certain circumstances, as well as put into place a number of other provisions that will change how providers and health plans engage with patients and each other with respect to price and coverage transparency, as well as billing. The following implementation guide is intended to help hospitals and health systems understand the new provisions in the law and corresponding regulations. The following sections provide:

- A summary of the various provisions;
- The effective date;
- Links to the legislation, regulatory text and additional federal guidance when available; and
- Frequently Asked Questions.

This implementation guide is a living document and will be updated regularly as the government releases additional information and as the AHA obtains answers to outstanding questions. Please check back frequently for updates. We will note in the text when an FAQ is new or updated.

Protections against Balance Billing for Certain Out-of-network Care

What It Is: Health care providers, including both professionals and facilities, will not be permitted to bill out-of-network patients for more than their in-network cost-sharing amount for certain services. These include:

- **Emergency services, including any services provided post-stabilization** until the patient is discharged or transferred. In some instances, the provider and/or facility may seek the patient's consent to balance bill for the post stabilization services. See the section on "notice and consent" for more information.
- **Scheduled professional services** when provided at an in-network facility unless the provider obtains the patient's consent to out-of-network services. For limits on which providers are eligible to seek consent, please see the section on "notice and consent."

Assessing Patient Cost-sharing for Out-of-network Services: Insurers must inform providers about the correct cost-sharing amount. While it is possible that the plan may provide the accurate cost-sharing amount when the provider runs an eligibility check, it is much more likely that the provider will need to first bill the plan in order to receive an adjudicated claim with the correct cost-sharing amount. The provider may then bill the patient the amount identified by the plan.

Effective Date: January 1, 2022

Potential Penalty for Violations: Providers face up to $10,000 in civil monetary penalties for each violation. States have primary responsibility for ensuring compliance. However, the federal government may investigate potential violations and issue penalties in some instances.

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021 ○ Sec. 102. Health insurance requirements regarding surprise medical billing. ○ Sec. 104. Health care provider requirements regarding surprise medical billing.
- **Regulations:** See the following sections of the Code of Federal Regulations, as discussed in the Interim Final Rule: Requirements Related to Surprise Billing; Part I
    - **ERISA:** 29 CFR Part 2590
    - **Individual and Fully Insured Markets:** 45 CFR 147, 45 CFR 149 ○
    - **Federal Employee Health Benefit Plans:** 5 CFR 890.114
- **Other Federal Guidance:** N/A **Frequently Asked Questions**

1) **How will I know if a patient is subject to these protections?** We continue to have substantial concerns regarding when a provider will know if a patient is subject to the balance billing protections. We are encouraging the federal government to require that health plans provide that information to the provider at the point an eligibility determination is done. However, this will require the creation of a new field and/or modifier. In the meantime, we encourage providers to err on the side of caution when sending bills to patients for out-of-network care, which may mean waiting until the claim is adjudicated before attempting to collect any cost-sharing.

2) **Can patients still choose to go out-of-network and pay out-of-pocket?** Yes (in some instances). Patients can continue to intentionally seek care from out-ofnetwork providers and may be subject to the cost of that care at their own expense. However, in some instances, an out-of-network provider may not be permitted to balance bill the patient. For example, some providers, such as assistant surgeons, anesthesiologists, and radiologists may not bill the patient directly. These providers may elect not to provide care to out-of-network patients or they may accept payment from the plan, subject to the remedies established under the law if a disagreement emerges over reimbursement.

3) **How much do I bill the patient?** Providers will need to bill the patient's health plan before learning definitively the amount to bill the patient.

4) **My state has a surprise billing law. How will I know whether the state or federal law applies?** Whether state or federal law (or both) apply depends on the circumstances of the case. Generally, state law applies to state-regulated products (e.g., fully insured individual and group market), and federal law applies to products that are primarily regulated at the federal level (e.g., self-insured/ERISA, FEHBP). However, in some states, a federally-regulated plan may opt into the state process. In addition, if the state law is less protective than the federal law, the federal law may "wrap around" the state law to provide comprehensive protection. An example of this is when a patient receives both emergency and post-stabilization services and the state law only provides protections for the emergency services. In that instance, the state law protections apply for the emergency services, and the federal law applies to the remainder of the care (up to the limits in federal law and regulations).

5) **Do the No Surprises Act provisions apply to narrow network health plans?** Yes, all of these rules apply to narrow network products as long as they are within one of the applicable insurance markets (self-funded, individual market, etc.).

6) **Do the No Surprises Act provisions apply to tiered networks when the provider is Tier 2 (i.e., not the highest benefit level). The patient would owe more than using a Tier 1 provider (which could be considered a surprise). Does this essentially do away with tiered products?** In the tiered network scenario, the provider is still in-network and therefore the ban on balance billing and the corresponding limits on cost-sharing to the in-network amount provisions would not

apply. The cost-sharing for tier 2 providers would be applied per the patient's coverage, including if it is higher than for a tier 1 provider.

7) **Do these provisions apply to health plans that do not have networks, such as reference-based pricing plans?** Yes; the provisions apply for emergency services. However, it is unlikely there will be a scenario where the provisions apply to scheduled non-emergency services given that those provisions only apply when the provider is out-of-network but the facility is in-network.

8) **Who determines whether the patient is receiving emergency services?** Patient care should continue in accordance with clinical best practices and other state and federal laws, such as EMTALA. The No Surprises Act does not change how providers triage patients in the emergency setting.

9) **Does it matter where the post-stabilization services are provided? Can they still be considered post-stabilization if provided in an outpatient department?** The regulations are clear that the setting is irrelevant for purposes of these patient protections. The protections against balance billing apply for post-stabilization services whether the patient is admitted or in an outpatient department or other setting.

10) **Do these provisions apply to clinical oversight billing done by pathologist for labs? These aren't pathology services but are labs done in the lab.** We interpret this question to mean the pathologist is doing a service that will ultimately be billed to the patient. If that is correct, we believe the answer is yes.

11) **Do ancillary providers include physical therapy, occupational therapy, behavioral health, and other non-physician providers?** The answer depends. The law does not permit certain ancillary providers from seeking consent to balance bill, including if they are providing items or services related to emergency medicine, anesthesiology, pathology, radiology and neonatology or if there is no other ancillary provider in the patient's network who can provide the item or service**.**

12) **Does this mandate apply to Medicaid/Medicare managed care plans?** No. The No Surprises Act does not apply to Medicaid or Medicare, including when operated through private commercial insurers through managed care arrangements.

Provider Payment

What It Is: The amount providers will be reimbursed is determined in one of the following ways: 1) as determined by state law, if state law applies; 2) as determined by an All-Payer Model Agreement in place in a state; 3) through negotiation between the plan/issuer and the provider; and 4) through a yet-to-be-implemented independent dispute resolution process. Plans must reimburse the provider directly; they may not send payment to the enrollee to then compensate the provider.

The regulations require plans and issuers to make an initial payment (or notice of denial) to providers within 30 calendar days of receiving a "clean claim." The departments note that they expect health plans and issuers to act in good faith but will consider additional standards if they become aware of abuse or gaming by plans/issuers. The regulations do not establish any requirements related to how much plans must reimburse providers; however, the departments note that they do not expect the initial payment to be treated as a "first installment." Rather, the payment should be an amount that the plan or issuer "reasonable intends to be payment in full based on the relevant facts and circumstances and as required under the terms of the plan or coverage."

Effective Date: January 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021 ○ Sec. 102. Health insurance requirements regarding surprise medical billing.
- **Regulations:**
  - **ERISA:** 29 CFR Part 2590**:** § 2590.716–4, § 2590.716–5 ○
  - **Individual and Fully Insured Markets:** 45 CFR 149: § 149.110, § 149.120
  - **Federal Employee Health Benefit Plans:** 5 CFR 890: § 54.9816–4T, § 54.9816–5T
- **Other Federal Guidance:** N/A

Frequently Asked Questions

1) **Does the law require plans to reimburse providers for emergency services at in-network rates?** No. Neither the law nor regulations establish a reimbursement standard. Instead, plans must remit an initial payment to providers within 30 days of receiving a clean claim. The provider may accept the payment or trigger a negotiation with the plan if it disagrees with the amount. If agreement still cannot be reached, either the plan or provider may seek to use the independent dispute resolution process.

2) **Are plans permitted to deny claims subject to the No Surprises Act because the patient does not have out-of-network benefits?** No. Plans may deny claims for other reasons, e.g., medical necessity, but they may not deny coverage of a service protected under the No Surprises Act because the enrollee's plan does include out-of-network coverage.

Independent Dispute Resolution Process

What It Is: Reimbursement for out-of-network services may be determined in one of several ways. The legislation defers to state law or policy if applicable. If no such policy applies, then the legislation defines the process through which reimbursement is determined. First, the provider may accept the initial payment made by the plan. Second, the health plan and provider may come to a mutually agreeable amount through routine negotiating procedures during a 30-day period that must be triggered within 30 days of when the plan sends the initial payment (or notice of payment denial). Finally, should either of these fail, the parties may bring an outstanding dispute to an independent dispute resolution (IDR) process established under the law. However, the parties can continue to negotiate during the IDR process and do not need to complete it if they can agree to reimbursement during this period. HHS has created a "Federal IDR Portal" to house all information about the process, as well as enable parties to trigger and complete the process.

IDR Timeline: If a provider and health plan cannot come to agreement on reimbursement by the conclusion of the 30-day open negotiation, either party may trigger the IDR process (referred to as "notifying"). The plan and provider then have three business days to jointly select the IDR entity to oversee the case; should that fail, the HHS Secretary has up to three business days to select one on their behalf. Within 10 days of the selection of the IDR entity, each party must submit an offer for reimbursement, as well as any supporting materials. The IDR entity must select one of the offers without modification as the final reimbursement determination within 30 days of the IDR entity having been selected. Once a determination has been reached in a case, the payer must remit reimbursement to the provider within 30 days.

The party that submitted the notification to initiate the IDR process may not submit another case for the same item or service involving the same other party during a 90day period after the initial notification. This is frequently referred to as a "cooling off" period. However, the party may hold such claims and then submit them for IDR within the fourday period after the 90-day "cooling off" period is over.

IDR Entity Factors for Consideration: The statute directs IDR entities to consider a number of factors when making their payment selection, including the qualifying payment amount (QPA) for the applicable item or service (see the QPA section of this guide for more information), information on the level of training, experience, quality and outcomes of the provider; the market share held by the provider and/or the plan; patient

acuity; teaching status, case mix, and scope of services of the provider; demonstrations of good faith efforts to enter into a network agreement with the other party; and, if applicable, past contracted rates between the parties during the previous four years. Either party may submit addition evidence it deems relevant, and the IDR entity may ask for other types of information. However, the IDR entities may not consider provider charges or rates paid by public programs, such as Medicare, Medicaid, the Children's Health Insurance Program or TRICARE.

In a notable departure from the statute, the regulations direct IDR entities to begin with the presumption that the QPA is an appropriate reimbursement amount and to select the offer closest to the QPA unless the other factors demonstrate why another amount is justified. On Dec. 9, 2021, the AHA, joined by the AMA, two hospitals, and two physicians, filed a lawsuit challenging these regulations. The lawsuit narrowly focuses on this one component of the regulation – the direction to the IDR entities to skew the decision in favor of the plans/issuers. Our challenge will not stop implementation of the critical patient protections for which the AHA advocated strongly for adoption. More information on the status of our legal case can be found here.

Batching of Items and Services. Providers may batch together like claims attributable to the same health plan that occur during a 30-day period. Claims may be batched if they are for the "same or similar" service as defined by billing codes.

Fees. Participating in the IDR process requires two types of fees: an administrative fee charged by the federal government for use of the ID process and an IDR fee that the IDR entity can charge for its services. Both fees are to be paid directly to the IDR entity, and the entity will remit the administrative fee to the federal government.

The calendar year 2022 administrative fees can be found at: Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act (cms.gov). For 2022, the administrative fee will be a flat $50. While the IDR entity fees are set by each entity, they must generally remain within a predetermined range consistent with annual guidance. For 2022, this range is set at $200 to $500 for a single determination and $268 to $670 for batched determinations.

Each party must pay the entire IDR entity fee upon submitting an offer and that amount is to be held in a trust or escrow account until the IDR entity makes its final determination. The wining party in the dispute receives a refund of the fee while the losing party forfeits the fee. For batched claims, the party with the fewest determinations in its favor is treated as the losing party. If there are equal numbers of determinations, the fee would be split evenly between the parties. The IDR entity can retain half of each party's fee if the parties reach an agreement before the end of the IDR process. In this scenario, the administrative fee would not be refunded. The departments seek comment on whether additional requirements should be imposed to ensure payment and collection of the administrative and IDR entity fees..

Public Posting of Information. The HHS Secretary must post publicly certain information about the IDR process on a quarterly basis, and the IDR entities are required to provide this information to the HHS Secretary for this purpose. Beginning in 2022, the HHS Secretary must post information on: the number of requests for IDR ("notifications"); the size of the provider practices or facilities submitting notifications; the number of cases that resulted in the IDR making a determination (versus being settled between the two parties); a description of the item or service at issue; where (geographically) the item or service was delivered; the amount each party offered through the IDR process; which offer was selected; the identity of the parties; the category and practice specialty of the provider or facility; the length of time it took the IDR entity to make a determination; the compensation paid to the IDR entity; the amount HHS has expended to carry out the IDR process; and other information as specified by the HHS Secretary. The statute does limit the HHS Secretary from posting certain privileged or confidential information.

Selection of IDR Entities. The statute outlines several eligibility criteria for IDR entities, and the Secretaries of HHS, Labor, and Treasury established a process for certification through regulation. IDR entities have relevant medical and legal expertise, as well as sufficient staffing to make determinations on a timely basis. The organization cannot be biased, e.g., a health plan, provider, or association of either plans or providers, and must meet other requirements, including certain fiscal integrity and confidentiality requirements. The Secretaries must ensure that a sufficient number of entities are chosen to ensure timely determinations, and entities will be certified for a five-year period, subject to revocation for noncompliance with any requirements.

The process to apply to become a certified entity is currently open at the Federal IDR Portal.

Effective Date: Immediately upon publication in the Federal Register. However, only claims for services on or after Jan. 1, 2022 are eligible for the process. Given the steps that must occur prior to triggering IDR, we expect that providers will not begin using the process before Mar. 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021 ○ Sec. 103. Determination of out-ofnetwork rates to be paid by health plans; Independent dispute resolution process.
- **Regulations:**
  - **ERISA:** 29 CFR § 2590.716—8
  - **Individual and Fully Insured Markets:** 45 CFR § 149.510 ○
  - **Federal Employee Health Benefit Plans:** 5 CFR 890 § 54.9816–8T
- **Other Federal Guidance:** ○ Federal IDR Portal
- AHA Litigation Page

Frequently Asked Questions

1) **How do I initiate the IDR process?** Providers, facilities, plans and issuers will initiate the IDR process through the Federal IDR Portal.

2) **How do I pick an IDR entity?** Selection of the IDR entity occurs through the Federal IDR Portal.

3) **What kinds of claims can be batched together?** The regulations limit the batching of claims that meet the following four criteria:

   - The item or service must be billed by the same provider or group of providers or facility as defined by the National Provider Identifier (NPI) or Taxpayer Identification Number (TIN);
   - The payment for the item or service must be made by the same group health plan or health insurance issuer;
   - The items or services must be the same items or services as defined as being billed using the same service code or a comparable code under a different procedural code system;
   - The items or services must have occurred within the same 30-business day period, or within the 90-day "suspension" or "cooling off" period between IDR requests for same or similar services.

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4) **Any advice on how I should evaluate claims for whether to take them to the IDR process?** The AHA anticipates providing member hospitals and health systems with insights into whether and when to use the IDR process. We are waiting, however, to see whether the courts or Administration change the regulations related to the consideration of factors.

5) **My state law provides protection for patients against balance billing but does not include any approach for addressing reimbursement disputes between plans and providers. For applicable state-regulated plans, would the state law apply for purposes of patient protection and the federal law apply for purposes of reimbursement or would one prevail entirely?** Yes, that is currently how the regulations intend for state laws and the federal laws to work. The state law applies first, and the federal law "wraps around" the state law if gaps remain. Therefore, it is possible that you may use the federal IDR process for a claim that is partially subject to state law. We are awaiting additional guidance from the government on the interaction between state and federal laws.

Qualifying Payment Amount

What It Is: The No Surprises Act established a calculation referred to as the "qualifying payment amount" (QPA) for two purposes: 1) to determine patient cost-sharing, and 2) as a factor for consideration by the arbiter as part of the independent dispute resolution process.

The statute defines the QPA as the plan or issuer's median in-network rate for the same or similar item or service that is provided by a provider in the same or similar specialty and in the same geographic region in 2019 trended forward. In the case of a selfinsured group health plan, the administering entity is treated as the plan for purposes of these provisions. The departments establish an approach for calculating the QPA when insufficient information exists, such as when a plan is new and did not contract with providers in 2019 or the item or service is new.

The first set of interim final regulations adopt the following methodology for calculating the QPA:

Methodology for Calculation: The regulations require that the median contracted rate be calculated by arranging in order from least to greatest the contracted rates of all plans of the plan sponsor (or of the administering entity, if applicable) or all coverage offered by the issuer in the same insurance market that meet the above criteria, and selecting the middle number. In cases of an even number of rates, the plan or issuer must average the two middle numbers. There must be at least three rates for purposes of this calculation.

The regulations establish the following definitions for purposes of calculating the QPA:

- **Contracted Rate.** The contracted rate is the total amount (included cost-sharing) that a plan or issuer has contractually agreed to pay a provider, including through a third-party administrator or pharmacy benefit manager. If the plan or issuer has multiple contracts with a provider and each have a different rate, each rate is counted separately for purposes of calculating the QPA. Rates from rented networks and arrangements with third-party entities to administer certain benefits also count as the plan's or issuer's rates for purposes of the calculation. However, rates associated with single case agreements, letters of agreement, or other similar arrangements between providers and plans/issuers do not count; according to the departments, such rates may not reflect market rates of "typical" contract negotiations.

- **Insurance Market.** Plans and issuers may only use rates from plans within the same insurance market. For purposes of the QPA calculation, this means: the individual market, small group market, or large group market. With respect to self-insured plans, the regulations define the term to mean all self-insured group health plans of the plan sponsor or, at the option of the plan sponsor, all

selfinsured group health plans administered by the same entity, e.g., a third party administrator. Medicare and Medicaid rates, regardless of whether they are administered by a managed care entity, are excluded from consideration. Similarly, rates for short-term, limited duration, account-based plans, and other forms of limited coverage are not included in the definition of applicable insurance.

- **Same or Similar Item or Service.** The regulations define "same or similar item or service" as a health care item or service billed under the same service code, or a comparable code under a different procedural code system, such as the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) coding systems. The departments note that the plans and issuers must take into account modifiers that affect payment rates, as well as calculate separate median contracted rates for providers and facilities.

- **Provider in the Same or Similar Specialty.** The regulations define "provider in the same or similar specialty" as the practice specialty of a provider. Plans/issuers only have to take into account the provider specialty if they contract for a service at different rates based on the provider's specialty. In these instances, the plan must identify the provider's specialty consistent with the plan's or issuer's usual business practice and then calculate separate QPAs by specialty. Similarly, if the plan does not vary the contracted rate by provider specialty, it does not need to calculate separate QPAs by specialty. For purposes of air ambulance services, all providers are considered to be a single provider specialty regardless of any variation in type of air craft or whether the air ambulance is hospital-based or independent.

- **Facility of the Same or Similar Facility Type.** The regulations distinguish only two types of facilities: hospital-based emergency departments and independent freestanding emergency departments. In other words, in instances where the plan or issuer contracts at different rates for emergency services based on the type of facility, it must calculate separate QPAs for those services. Otherwise, the regulations do not permit plans and issuers to account for other facility characteristics when determining which rates to use in the calculation. The regulations specifically give as an example academic medical centers and teaching hospitals and state that they do not believe patients should incur higher cost-sharing for emergency services because some types of facilities have different characteristics that may result in higher contracted rates.

- **Geographic Regions.** Plans and issuers must only include rates from within the same geographic region. For purposes of the calculation, each metropolitan statistical area (MSA) in a state constitutes its own region, with all other portions of the state combined to form a single region. If a plan or issuer does not have sufficient contracted rates in a given MSA, the plan/issuer must consider all

MSAs in the state as one region. If this approach still does not provide enough data points, the plan or issuer must calculate the QPA based on all MSAs in the appropriate Census division and one region consisting of all other portions of the Census divisions. For air ambulances, the region is determined based on where the patient was picked up. In addition, for air ambulances, the geographic regions are determined at the state level (all MSAs together as a single region with all other areas of the state as another region), escalating to the Census division if necessary.

- **Non-Fee-for-Service Contractual Arrangements.** The regulations address how to determine the rate for contracts that are based on bundled payment, capitation, or other forms of non-fee-for-service arrangements. The regulations direct issuers to use the internal, underlying fee schedule amount. They note that plans and issuers often use an underlying fee schedule to calculate patient costsharing or for other purposes, such as compliance with the transparency in coverage regulations. If such an underlying fee schedule does not exist, the plan or issuer must use a derived amount, which is the price that a plan or issuer assigns an item or service for purposes of internal accounting, reconciliation with providers, or for submitting required data to regulators. This is the same approach that plans and issuers must use in similar circumstances for purposes of implementing the transparency in coverage regulations.

  The regulations also specify that plans and issuers must exclude risk sharing, bonus/penalty and other incentive-based and retrospective payments or payment adjustments, which they believe are consistent with how patient cost-sharing is typically determined in in-network scenarios when providers are reimbursed under value-based arrangements.

- **Special Rules for Unit-based Services.** The departments note that for some services plans and issues may determine reimbursement by multiplying the contracted rate by another unit, such as time or mileage; the regulations therefore require that plans and issuers apply these multipliers after identifying the median contracted rate for the base unit. The regulations also specifically address anesthesia and air ambulance services.

  - **Anesthesia.** Anesthesia services are generally reimbursed based on a combination of a negotiated base rate that is then adjusted by the number of units used, time and the physical status of the patient. Plans and issuers must first calculate the median contracted rate for the anesthesia conversion factor for the same or similar item or service (trended forward as appropriate) and then apply the necessary modifiers to reflect the base units, time units and physical status modifier units.

  - **Air Ambulance.** Plans and issuers generally reimburse air ambulance services based on a base rate for the air ambulance service code

multiplied by the number of miles while the patient is onboard ("loaded"). To calculate the QPA for air ambulance services, the plans and issuers must first calculate the median contracted amount for the air mileage service code (trended forward as appropriate) and then multiply it by the number or loaded miles.

- **Indexing.** The QPA for 2022 is the 2019 QPA trended forward by the consumer price index for all urban consumers (CPI-U), and will be indexed to CPI-U in perpetuity. The regulation provides specifications for calculating the index rate annually. In order to ensure uniformity, plans and issuers will calculate the increases using factors determined by the Treasury Department and the IRS, and published in guidance by the IRS.

Cases with Insufficient Data: Plans and issuers must have at least three contracted rates on Jan. 31, 2019 to calculate the QPA. The regulations lay out alternative processes for determining the QPA in instances where the plan or issuer does not have sufficient data from 2019, including in instances where the item or service is new and for which neither the plan/issuer nor an independent database would have any information to use to calculate a QPA. These include: use of data from a subsequent year, use of independent databases, and use of a derivative of Medicare rates for new items and services.

- **Use of Data from a Subsequent Year.** If a plan or issuer gains sufficient data in subsequent years, it must use the data from the first year it has sufficient data to calculate the QPA. The rates must have been in place on Jan. 31 of the year immediately preceding the year in which the data will be used, and the rates must account for at least 25% of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or administering entity). The departments note that the 25% rule is intended to prevent "selective contracting practices" by plans and issuers that might inappropriately depress the QPA.

- **Use of Independent Databases.** In instances where a plan or issuer does not have sufficient information to calculate the QPA, they must use payment information from an independent database free of any conflicts of interest. The departments do not identify a single database; rather, they establish criteria to identify an eligible database. State all-payer claims databases are categorically eligible.

  Other third party databases may be eligible if they meet a number of criteria. First, the databases must not be affiliated with or owned or controlled by any issuer or provider, or any member of the same controlled group as the plan/issuer or provider. The departments discuss several scenarios that would deem a plan ineligible based on affiliations and seek comment on whether they also should disqualify any databases owned by, controlled by, or affiliated with a

plan sponsor or third party administrator. Second, the database must have sufficient information reflecting in-network amounts, but the rule does not establish a threshold or definition for "sufficient." Finally, the regulations require that the database have the ability to distinguish amounts paid to providers and facilities by commercial payers so as to not include rates from payers excluded from consideration (e.g. Medicare, Medicaid).

The regulations describe how plans and issuers must use this data to calculate the QPA, including prescribing the data that must be used, defining the appropriate year for the data, and how the data must be trended forward. Plans and issuers are required to use a consistent methodology when accessing information from databases for purposes of calculating the QPA. Finally, plans and issuers are responsible for the fees associated with accessing data from the database.

- **New Items and Services.** The regulations establish an approach for calculating the QPA when neither the plan/issuer nor an independent database has sufficient data to calculate the QPA because the item or service is new or the associated code was "substantially revised." In these instances and until sufficient data is available, plans and insurers must use a code for a related service and then adjust it based on the ratio between the Medicare rate for the new code and the Medicare rate for the related code.

Requirements on Insurers to Share Information with Providers: The law requires plans and issuers to share information with providers about the QPA and directed the departments to specify the information to be shared and when to share it. The regulations require plans and issuers to provide in writing, either on paper or electronically, to the provider: that the QPA is serving as the recognized amount for purposes of determining cost-sharing; the value of the QPA; a statement certifying that the QPA was calculated consistent with these regulations; and a statement that the provider may enter into a 30-day open negotiation period with the plan or issuer. Providers may request additional information from the plan or issuer, such as whether non-fee-for-service rates were included in the calculation, whether a related service code was used, and, if applicable, which database was used to calculate the QPA. If applicable and at the provider's request, the plan or issuer must provide a statement that the contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

Effective Date: January 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021
  - Sec. 103. Determination of out-ofnetwork rates to be paid by health plans; Independent dispute resolution process.

- **Regulations:** See the following sections of the Code of Federal Regulations, as discussed in the Interim Final Rule: Requirements Related to Surprise Billing; Part I
    - **ERISA:** 29 CFR Part 2590
    - **Individual and Fully Insured Markets:** 45 CFR 149.140
    - **Federal Employee Health Benefit Plans:** 5 CFR 890.114
- **Other Federal Guidance:** N/A

Frequently Asked Questions

1) **Is the QPA what I should expect in reimbursement from the plan?** The law and regulations did not establish the QPA for purposes of provider reimbursement. However, there is nothing prohibiting a plan from remitting the value of the QPA to the provider as the initial payment amount if the plan believe that constitutes an appropriate amount in reimbursement for the given provider/service. However, providers are not obligated to accept the initial payment as payment in full and may negotiate with the plan to obtain fair compensation. Should negotiation fail, the provider may submit the claim for adjudication through the IDR process.

2) **When will the insurer share the QPA with providers?** The insurer must send the QPA information, along with an initial payment (or note of denial), within 30 days of receiving a clean claim.

3) **What happens if the insurer never sends the QPA to the provider?** The insurer would be in violation of the law and regulations. Providers would have the option to alert regulators for potential oversight and enforcement actions.

4) **How can we be sure a plan calculated the QPA correctly?** We do not believe it is possible for a provider to know with certainty. If you have reason to believe that a plan is incorrectly calculating the QPA, we recommend raising your concerns with the appropriate state regulators.

Notice and Consent Process

What It Is: The law and regulations permit patients to waive balance billing protections if the out-of-network provider obtains the patient's consent in two narrowly prescribed circumstances: 1) post-stabilization, and 2) certain scheduled services provided by an out-of-network provider at an in-network facility. The law prohibits the use of notice and consent for certain services, including emergency services (with the exception of some services provided post-stabilization as discussed below), 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, items and services for which no in-network provider is available in the facility, and certain ancillary services as described in more detail below. Notably, providers do not need to use the notice and consent process in instances where the No Surprises Act patient protections do not apply, such

as when both the provider and facility are out-of-network, for non-emergency care. Providers and facilities must use the standard notice and consent guidance and forms provided by the Centers for Medicare & Medicaid Services' (CMS) (CMS Form10780 available here).

Services for Which Notice and Consent May and May Not Be Used: The notice and consent process may be used for certain services as long as defined conditions are met. Specifically, subject to conditions, providers may seek a patient's consent to balance bill for out-of-network post-stabilization services and certain scheduled, nonemergency scheduled services provided at in-network facilities. However, the law and regulations prohibit certain out-of-network providers from balance billing when delivering some services, including:

- Items and services related to emergency medicine, anesthesiology, pathology, radiology and neonatology, whether provided by a physician or nonphysician practitioner;
- Items and services provided by assistant surgeons, hospitalists and intensivists;
- Diagnostic services, including radiology and laboratory services; and
- Other items and services provided by a nonparticipating provider if there is no participating provider who can furnish such items or services at such facility.

Conditions for Use of Notice and Consent for Post-stabilization Services. Out of network providers and facilities may balance bill patients for services provided post stabilization when the following conditions are met:

1. The patient's attending physician or treating provider determines that the patient can travel to an in-network facility using non-medical or non-emergency medical transportation. This determination must be based on all relevant factors, including the type of available transportation, travel distance, travel conditions and the patient's ability to pay for such transportation;

2. The patient gives informed consent to the out-of-network care (in accordance to the stipulated notice and consent process described below) and agrees to be balance billed. The attending physician or treating provider will determine if the individual or the individual's personal representative is able to provide informed consent and, in doing so, must take into account factors such as a patient's mental and emotional state, mental or behavioral conditions, substance use, language access and literacy levels, and cultural or other contextual factors, including historical inequities for underserved communities. The individual must be able to consent freely, voluntarily and without undue influence, fraud, or duress;

3. The provider or facility satisfies other conditions laid out by the departments; and

4. The providers and facilities comply with any relevant state law, including laws that prohibit patients from waiving balance billing protections.

The decision of the attending physician or treating provider in assessing whether the post-stabilization conditions are met is binding on the facility.

Notice and Consent Process Requirements: The law and regulations requires that out-of-network providers seeking to balance bill a patient in one of the permissible scenarios must adhere to a prescribed notice and consent process. Providers must use a standard form and follow a prescribed timeline, among other requirements.

- **Timing and Process.** The regulations require that a patient receives the notice with the request for their consent to be balance billed at least 72 hours before the service or treatment is to be delivered. For same-day services, the notice must be provided at least three hours prior to receiving the service or treatment. The regulations require that providers/facilities must convey these forms to the patient separately from other documents, and a copy of the signed notice and consent form must be provided to the patient or authorized representative in a form of their choosing (paper or electronic). In addition, a representative of the provider/facility must be physically present or available by phone to answer questions.

- **Use of a Standard Form.** Facilities and providers must use the standard form provided by HHS with only minimal modification. The forms can be accessed on CMS' webpage. The form must include such information as: the name of the out-of-network provider or facility, the provider's contact information, a good faith estimate of charges, information on any care management limitations that may be imposed by the patient's health plan/issuer, and the contact information for appropriate state and local agencies to report any potential violations. The forms must collect the date the patient receives the notice, as well as the date the patient (or their authorized representative) provides consent.

- **Good Faith Estimate of Charges.** The law specifically requires that the notice and consent form include a good faith estimate of the out-of-network charges. The regulations require that the good faith estimate reflect the amount the provider or facility expects to charge for furnishing such items or services, even if the provider or facility intends to first bill the plan/issuer. In addition, the regulations stipulate that the provider/facility must use the same process to develop the good faith estimate as will be required to meet the other price transparency provisions in the No Surprises Act.

- **Prior Authorization and Other Care Management Limitations.** The regulations require that the provider/facility include in the notice information about plan/issuer prior authorization or other care management limitations. The departments note that providers and facilities may be challenged to get specific plan/issuer prior authorization and care management requirements and could satisfy this with a general disclosure. However, they encourage providers and facilities to directly contact the plan to obtain this information.

- **Specific Requirements Related to Services Provided Post-Stabilization.** The regulation specifies that in the event of post-stabilization services furnished by an

out-of-network provider at an out-of-network facility, the facility must include in the notice and consent the good faith estimates for all items and services provided by out-of-network providers. The regulation also specifies that for the in-network facility, the notice must include a list of any in-network providers who are able to furnish the items or services.

- **Language Access.** The regulations generally require that providers and facilities provide notice and consent in the top 15 languages in a state or geographic region in which the applicable facility is located. Providers and facilities will need to translate the notice and consent form into the top 15 applicable languages. If an individual's preferred language is not among the top 15 languages for which the documents are available, the notice and consent requirements cannot be met unless the provider or facility furnishes the individual with a qualified interpreter. Providers and facilities also are required to comply with other applicable state and federal laws regarding language access.

Managing Notice and Consent Forms for Out-of-Network Providers by Facilities. Facilities have different responsibilities depending on whether the services are post-stabilization or scheduled non-emergency services. For poststabilization services, the facility must manage the notice and consent process for all out-of-network providers engaged in the patient's care. For scheduled, nonemergency out-of-network professional services provided at an in-network facility, the facility has the option – but is not required – to complete the process on behalf of the providers. In addition, out-of-network professionals can either coordinate and use a single notice and consent process, or conduct their own process. In the case where multiple out-of-network providers use the same notice and consent forms, the patient can choose to waive their rights for certain services but not necessarily all services.

Requirement that Providers and Facilities Notify Plans/Issuers when Notice and Consent is Used. The regulation requires that providers and facilities notify plans/issuers when the balance billing protections apply for a service and the notice and consent process was used. The provider/facility must provide a copy of the signed notice and consent document to the plan/issuer. With regard to post-stabilization services, it is the facility's responsibility to notify plans/issuers when a notice and consent process is used and that all the required conditions are met for a post-stabilization patient.

Patient Option to Refuse or Revoke Consent. Patients can refuse or revoke consent to waive their balance billing protections in writing before the care is provided. If the patient revokes consent, the balance billing protections would apply. For scheduled services but not post-stabilization services, providers are not required to treat patients who refuse to consent to be balance billed unless no in-network provider is available to provide the care.

Document Retention Requirements: Providers/facilities must retain signed notice and consent documents for seven years. Facilities can retain signed notice and consent documents for out-of-network providers upon agreement with those providers.

Effective Date: January 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021
  - Sec. 104. Health care provider requirements regarding surprise medical billing.
- **Regulations:** See the following sections of the Code of Federal Regulations, as discussed in the Interim Final Rule: Requirements Related to Surprise Billing; Part I
  - **ERISA:** 29 CFR Part 2590
  - **Individual and Fully Insured Markets:** 45 CFR 149.410(b)(2), 45 CFR 149.450(c)
  - **Federal Employee Health Benefit Plans:** 5 CFR 890.114
- **Other Federal Guidance:** N/A

Frequently Asked Questions

The following questions and answers are based on the AHA's best understanding of the law and regulations at this time. They should not be considered legal advice, and we encourage hospitals and health systems to consult with their legal counsel to ensure compliance with all federal laws and regulations. We will continue to seek clarity from the federal agencies on these and other questions.

Notice and Consent in the Context of Emergency, including Post-Stabilization, Services

1) **How do the No Surprises Act notice and consent policies interact with EMTALA?**

   The No Surprises Act does not establish any requirements on providers or facilities that are in violation of EMTALA.

   The No Surprises Act prohibits facilities and providers from balance billing for emergency services. For purposes of this prohibition on balance billing, the No Surprises Act builds on the definition of "emergency" in EMTALA to include poststabilization services. The No Surprises Act does, however, enable certain outofnetwork facilities and providers the ability to use a notice and consent process to seek the patient's consent to balance bill for certain services that are provided poststabilization. However, this is an option for facilities and some providers; it is not a requirement.

The ability for facilities and certain providers to seek patient's consent to balance bill only applies to certain services provided post-stabilization (as defined by EMTALA) when a number of conditions are met. More information on these conditions can be found in the AHA's Implementation Guide under "notice and consent."

2) **What are the conditions that must be met for an out-of-network facility or provider to use the notice and consent process for post-stabilization services**?

Four conditions must be met prior to an out-of-network facility or provider seeking a patient's consent to balance bill:

1. The emergency treating physician/provider must determine that the patient is stable enough for transfer to an in-network facility using nonmedical/nonemergency forms of transportation taking into consideration the distance, affordability and travel conditions.
2. The out-of-network facility or providers must satisfy all the prescribed notice and consent requirements stipulated in the No Surprises Act and implementing regulations.
3. The treating emergency provider must determine if the individual or the individual's personal representative is able to provide informed consent. In doing so, the treating provider must take into account factors such as a patient's mental and emotional state, mental or behavioral conditions, substance use, language access and literacy levels, and cultural or other contextual factors, including historical inequities for underserved communities.
4. The out of network facility or provider must also satisfy other conditions laid out by the federal government and comply with any relevant state law, including laws that prohibit patients from waiving balance billing protections.

All of these conditions must be met before an out-of-network facility or provider can use the notice and consent process for a post-stabilization patient.

3) **Does an out-of-network facility or provider need to meet all of the notice and consent requirements prior to transferring an out-of-network patient to an innetwork facility?**

No. Completing the balance billing notice and consent process is not a condition for transferring a patient. The only reason an out-of-network facility or provider would need to follow the notice and consent requirements prior to transfer is if they wanted to seek the patient's consent to balance bill for any eligible services prior to transfer.

We note, however, that other federal and state laws and regulations may apply to patient transfers. The No Surprises Act does not alter any other rules governing patient transfers.

4) **If a post-stabilization patient refuses to consent to balance billing, do patient balance billing protections still apply?**

If the post-stabilization patient does not consent to balance billing and the provider proceeds with delivering the care, the balance billing protections will apply. However, the No Surprises Act does not require the out-of-network facility or provider to continue treating the patient and may instead seek to transfer the patient to innetwork providers.

5) **For purposes of the No Surprises Act requirements, who is responsible for determining that a patient is stable enough to be transferred to an in-network facility?**

This decision lies solely with the out-of-network emergency treating physician/provider and not the facility or health plan (or any other party). Note: there may be other laws and regulations governing the transfer of patients, and this question and answer relate only to the No Surprises Act provisions.

6) **Will the out-of-network facility be paid for post-stabilization services if the patient both refuses consent to be balance billed and refuses to be transferred for an in-network facility?**

The No Surprises Act does not require out-of-network providers to treat outofnetwork patients. However, if the out-of-network facility or provider moves forward with delivering care after the patient refuses consent, the balance billing protections, including the provisions related to reimbursement, remain in place. Specifically, the preamble to the regulation states that, if a patient "does not provide (or revokes) consent to waive their balance billing protections, those protections remain in place. A provider or facility may, subject to other state or federal laws, refuse to treat the individual if the individual does not consent. However, the cost-sharing and balance billing protections applicable to plans, issuers, providers and facilities would apply with respect to any items or services furnished by the provider or facility subsequent to the provision of the notice, and absent consent." (see 86 FR 36905-6)

7) **If a provider complies with the federal notice and consent process, will they also be considered in compliance with any state laws regarding notice and consent?**

Not necessarily. We encourage facilities and providers to consult with their legal counsel regarding the interaction between federal and state laws that may apply. Meanwhile, the AHA has encouraged the federal government to provide additional guidance related to the interaction between state and federal law.

7) **Will there be further guidance regarding the requirement that the treating provider take into account cultural, historical or contextual factors in determining whether a patient is able to consent?**

The regulations indicate that further guidance may be forthcoming; however, such guidance is not likely to be released before the law goes into effect on Jan. 1, 2022.

8) **When both the facility and the providers are out-of-network, which entity – the facility or provider(s) – is responsible for generating the good faith estimate to be included as part of the notice and consent process for post-stabilization patients?**

Out-of-network facilities are responsible for generating the good faith estimates for all of the out-of-network providers who are seeking consent to balance bill a post-stabilization patient. Note, the answer is different when the care is for a scheduled service where the facility is in-network but one or more of the providers is out-of-network. We encourage those interested in that scenario to look at the next section related to how these rules apply to non-emergent care.

9) **If the facility is in-network but the providers are out-of-network, what responsibilities does the in-network facility have regarding the notice and consent process for a post-stabilization patient?**

In this instance, the out-of-network provider is responsible for their own notice and consent process unless the in-network facility has agreed to assume this responsibility of their behalf.

10) **If a hospital does not have an emergency department (ED), do the balance billing protections apply, including the requirement to use the notice and consent process if the provider seeks to balance bill the patient for services?**

While the No Surprises Act applies to hospitals, we believe it is possible that these requirements would not apply if the facility does not offer emergency-level care (and, therefore, they are providing neither emergency services, nor post-stabilization services). However, we note that this scenario has not been explicitly addressed in the law or regulations, and we believe any hospital in this situation should consult with their legal counsel, particularly to consider instances where a patient may present to the facility believing they can obtain emergency services or an emergency patient is transferred to the facility due to their unique capabilities. In this instance, the facility could provide emergency services even without having an emergency department.

11) **Is it correct that you have to give a good faith estimate of potential charges in the notice and consent forms for post-stabilization services, including for those patients who become inpatients?**

Yes. A good faith estimate of charges is always required as part of the notice and consent process.

12) **If a post-stabilization patient consents to treatment at the out-of-network facility and the anesthesiology is out-of-network, can the out-of-network anesthesiologist balance bill the patient?**

No. Anesthesiology is an ancillary service for which balance billing protections always apply. In this scenario, while the patient may consent to be balance billed for certain out-of-network care, they cannot waive their balancing billing protections for anesthesiologist services, and therefore, the anesthesiologist could not balance bill the patient under any circumstance.

13) **More than likely, patients will not provide consent to be balance billed for post-stabilization services. Do you agree?**

Yes. We also note that the government in the preamble to the regulations has stated its expectation that this will be an infrequent occurrence.

14) **An out-of-network patient presents to a hospital emergency department and is treated and deemed stable by the treating physician. The treating physician believes the patient can be discharged to home with an antibiotic prescription. Does the provider need to complete the notice and consent process before the patient can be discharged?**

No. First, the notice and consent process is never required but instead is an option for providers interested in balance billing a patient in certain, limited circumstances of out-of-network care. Second, in this instance, it appears as though the patient only received emergency services, which are not eligible for notice and consent.

15) **An out-of-network patient presents to a hospital emergency department with a non-emergent condition. Can the emergency department use notice and consent to bill for providing non-emergent services to an individual who presents with a minor condition after they have been triaged?**

While the regulations do not address this specific scenario, we believe the balance billing protections would apply to any care rendered in the emergency department. However, we are requesting clarity from the government on this question.

16) **Will hospital emergency departments be required to give out-of-network notices to patients once they are stabilized if they are being transferred to a non-network hospital for more specialized care?**

Both the sending and receiving out-of-network facilities must give the patient the one-page notice of rights with respect to balance billing. This is separate, however, from the notice that an out-of-network facility or provider may give a patient when seeking to balance bill them for care. Out-of-network facilities and providers are never required to use the notice and consent process; instead, they may use it at

their option in certain limited circumstances for which they wish to balance bill the patient.

In the scenario presented in this question, it appears as though the patient requires additional post-stabilization services that are only available at another out-of-network facility. Whether either out-of-network facility is able to use the notice and consent process to balance bill for these services depends on whether the patient meets all of the criteria for notice and consent (see question 2 above or the section on notice and consent in the AHA's Implementation Guide). For example, if the patient needs to be transferred using emergency medical transportation to another out-of-network facility, then the notice and consent requirements would not be available to either facility because one criteria for the use of notice and consent is that the patient be able to move using non-medical transportation. If the patient's condition changes, it is possible the receiving out-of-network facility may then be able to seek the patient's consent to balance bill. We also note, however, that the No Surprises Act does not compel an out-of-network provider to deliver care to an out-of-network patient.

17) **Who is responsible for giving the patient notice of their balance billing rights when the patient is being transferred via emergency air evacuation to another facility**?

Each out-of-network facility or provider that may bill the patient for care must provide the patient with a notification of their rights with respect to balance billing.

18) **If an out-of-network hospital emergency department treats and stabilizes a patient before transferring them to an in-network hospital for further care, is the patient still protected from balance billing?**

Yes. The balance billing protections would apply to all emergency services provided to the patient regardless of whether the patient receives additional care at an in-network facility.

19) **The hospital emergency department arranges air transport for an out-of-network patient to an in-network facility. What are the responsibilities of the hospital at this point in terms of notice and consent for the medical transport?**

In this instance, it is unlikely that the out-of-network provider could use the notice and consent process to balance bill the patient as all of the services provided to the patient are likely to qualify as emergency services. The No Surprises Act does not change any other federal or state laws or regulations that may otherwise apply to decision-marking regarding the transfer of a patient.

20) **If an emergency department patient has imaging services that are read by independent radiologists, is the hospital responsible for knowing if those radiologists are in-network with the patient's plan? In addition, would the**

hospital then have to give the required out-of-network patient notice with radiologist fee estimates once he/she is stabilized?

The law prohibits certain providers from ever balance billing a patient, and this includes radiologists. Therefore, the notice and consent process is not available to the radiologist, and the hospital must only ensure that they provide the patient with a notice of their rights with respect to balance billing, which is a different notice than what is part of the notice and consent process.

21) **For the emergency department, including emergency physicians, are both the notice and consent forms required, and are they required for all patients?**

Providers must give all patients enrolled in a form of comprehensive commercial coverage (e.g., employer-based coverage, individual market, etc.) a notice of their rights with respect to balance billing. This notice is different than the notice and consent process, which is what an out-of-network provider uses when they want to obtain a patient's consent to balance bill them for their care. However, the notice and consent process cannot be used for emergency services. Therefore, neither the emergency department nor the emergency personnel may use the notice and consent process to balance bill.

22) **What if an out-of-network patient requires an emergency psychiatric evaluation in the hospital emergency department and the emergency psychiatric evaluation is performed by a contracted provider that is a Community Mental Health Center, does the ban on balance billing apply to all providers in this scenario?**

Yes, the ban on balance billing applies because this is an emergency service, regardless of whether the provider is contracted to the facility.

Notice and Consent in the Context of Non-Emergency Services

1) **What are the circumstances for which a patient can waive their balance billing protections through notice and consent?**

In certain limited instances may out-of-network facilities and providers seek to balance bill a patient. For example, facilities and providers may never use the notice and consent process to balance bill a patient for emergency services (with some exceptions for post-stabilization services), nor for many ancillary services. For those services that are eligible for notice and consent, the out-of-network facility or provider must use the forms provided by the government and deliver them consistent with the timing and delivery requirements established in regulation. A key

element of the notice is a good faith estimate of charges. We point facilities and providers to the implementing regulations, as well as a summary of requirements included in the AHA's Implementation Guide.

2) **Where might one find the CMS notice and consent form and instructions to be used in the process?**

   The CMS forms can be found here: CMS-10780 | CMS. You will need to download and unzip the files.

3) **Do you expect the departments to establish additional conditions for the notice and consent process?**

   We are not aware of other conditions that the departments may be contemplating for the notice and consent process at this time.

4) **In the case of an out-of-network provider at an in-network facility, who is responsible for providing notice and obtaining consent to balance bill for elective procedures?**

   Each provider is responsible for their own notice and consent process unless the out-of-network provider and the in-network facility agree that the facility will take on the notice and consent process. The facility, however, does not have to agree to coordinate the notice and consent process.

5) **If a patient is seeking elective care from out-of-network providers at an out-of-network facility, does the provider need to use the notice and consent process in order to balance bill the patient?**

   No. The prohibition on balance billing does not apply for non-emergency services provided by an out-of-network provider at an out-of-network facility.

6) **Could plans use the No Surprises Act requirements to their advantage to change the landscape of provider plan contracts? For example, could health plans drop out-of-network coverage entirely or reduce coverage?**

   Nothing in the law bars health plans from attempting to change the nature of provider and facility contracts, consistent with the terms of those contracts. We have shared our concerns about this occurring with the departments.

7) **A patient's health coverage includes out-of-network benefits. Does the No Surprises Act balance billing protections apply or do the provider and plan process any claims for service against the out-of-network benefit, including determination of patient cost-sharing?**

Yes, the balance billing protections would apply, and the provider would need to use the notice and consent process if it wished to seek the patient's consent to be balanced bill. The fact that a patient has an out-of-network benefit within their health plan coverage is irrelevant.

8) **If an in-network provider is not available at an in-network facility, can an out-of-network provider use the No Surprises Act notice and consent process to request the patient waive their balance billing protections and be balanced billed for the care? If not, is the provider required to treat the patient or can they decline?**

   In instances where no in-network provider is available, the out-of-network provider is not permitted to use the notice and consent process. However, the out-of-network provider is not required to treat the patient.

9) **A patient is being treated at an in-network facility and there is no in-network provider available for the originally planned course of treatment; however, there is an in-network provider available offering an alternative treatment that does not compromise the quality of care. Do the notice and consent requirements apply in this scenario?**

   No. Notice and consent is available in limited instances for out-of-network providers who are interested in balance billing the patient. If there is no out-of-network care, there can be no balance billing and, therefore, the notice and consent process is not applicable. However, nothing in the No Surprises Act changes any rules related to patient consent to change a treatment regimen, to the extent such rules exist in other state or federal laws.

10) **The patient is seen at an in-network facility and is referred to the hospital's outpatient lab, which is out-of-network for the patient's health plan. Is the innetwork facility required to go through the No Surprises Act notice and consent process to balance bill the patient for the out-of-network laboratory service, or is the out-of-network lab service, even when hospital-based, a service for which the ban on balance billing applies?**

    Labs may never balance bill out-of-network patients when those patients are receiving emergency services or being seen at an in-network facility. Therefore, the notice and consent process is not available to the lab in this scenario.

11) **A patient is being treated at an in-network facility for a scheduled procedure. The in-network facility learns after the fact that one of the providers treating the patient is out-of-network for that patient's health plan. Has the in-network facility violated the No Surprises Act in any way, including the notice and consent requirements, if they did not know at the time of the patient's treatment that one of the providers was not in-network?**

As long as the facility provided the patient with their notice of rights regarding balance billing and the out-of-network provider did not balance bill the patient for services without obtaining the patient's consent, we do not believe a violation of the No Surprises Act would have occurred in this scenario.

12) **An out-of-network patient is receiving telehealth services from a provider in a different state. Can the out-of-network provider for the telehealth services balance bill the patient? Which balance billing protections would apply: state law (if it exists) of the location of the provider, state law (if it exists) of the location of the patient, or federal law?**

If the patient is choosing to go out-of-network for scheduled, non-emergent telehealth services, the ban on balance billing likely does not apply. This may change, however, if the patient is accessing the telehealth service as part of a visit at an in-network facility. In that case, the ban on balance billing would apply unless the provider was eligible for and used the notice and consent process. In this instance, while we encourage providers to consult with their counsels regarding which laws apply for a specific circumstance, we would expect that the laws of the location of both the facility and patient would apply.

13) **An in-network provider delivers care to a patient that the eligibility check suggests is covered by the patient's health plan. However, upon billing the patient's health plan, the provider learns that some of the services are not covered by the patient's coverage. Is the provider able to bill the patient without having completed the notice and consent process since the balance billing protections do not apply to either in-network care nor to non-covered services? Would the provider be in violation of the good faith estimate requirements?**

Generally, the balance billing protections (and therefore the ability to use notice and consent) only apply to covered services. We do believe it's possible, however, for this to run afoul of the good faith estimate requirements. However, we believe further guidance is needed in this area.

The regulation is unclear as to how providers should proceed when a good faith estimate was not produced for services due to a prior indication that such care was covered. The rule establishes that a provider acting in good faith and with due diligence is not considered to be in violation of the good faith estimate rules merely because of an omission of a service, but fails to specify how to treat services in which an eligibility response provides incomplete or incorrect information. The AHA has raised this issue with CMS and will provide an update once we have additional information.

14) **If both the hospital and the providers (physicians at the hospital) are all out-of-network, would the ban on balance billing apply and the services be eligible for notice and consent?**

No, if the patient is choosing to go to an out-of-network facility and providers for non-emergent care, the ban on balance billing would not apply and, therefore, the notice and consent process would not be necessary/applicable.

15) **Does the ban on balance billing and notice and consent process apply to an out-of-network provider at an out-of-network facility or private office?**

No. See response to Q14 above. In addition private physician's offices are not considered facilities. Therefore, the balance billing rules do not apply to services delivered at private physician's offices.

16) **If you are in a private practice and see a patient for exam, testing, or office procedure, do they need to be notified in advance and do they need to sign consent.**

The balance billing rules do not apply to services provided at private physician's offices that are not part of a hospital outpatient department or other facility outlined in law and regulation; therefore, the notice and consent policies do not apply.

17) **The language in the rule was not clear about the notice and consent provisions and estimates for out-of-network services in out-of-network facilities. Could you clarify?**

There appear to be two different issues in this question: 1) balance billing prohibition and the related notice and consent process, and 2) good faith estimates. The answers regarding which apply to out-of-network facilities are different.

For non-emergent services, the balance billing protections do not apply when the facility is out-of-network; therefore, the notice and consent process also does not apply.

Separately, good faith estimates are required for uninsured or self-pay patients for all instances of care scheduled at least 3 days out or upon request by the patient. While generally an out-of-network provider would not need to provide this estimate to an insured patient, it is possible that the patient would prefer to self-pay and forego their coverage. In that instance, the out-of-network facility would be required to provide a good faith estimate for any scheduled services.

18) **Are hospitals required to provide notice and consent for out of network care for Medicare Advantage and Medicaid managed care patients?**

No. The Medicare and Medicaid programs prohibit balance billing, and, as such, neither the No Surprises Act prohibitions on balance billing, nor the notice and consent process to seek a patient's consent to waive their rights, apply to patients enrolled in these programs. This answer is the same whether the patient is enrolled

in the traditional fee-for-service Medicare or Medicaid program or receives their benefits through a managed care entity.

19) **Which No Surprises Act requirements apply to reference-based pricing plans (also known as no-network plans)?**

Patients in no-network plans are protected from balance billing for emergency services. However, given that there are no in-network facilities, we do not believe that the prohibition on balance billing applies for scheduled, non-emergent care for patients with these types of plans.

With respect to good faith estimates, we believe that if the patient intends for the facility/provider to submit the claim to their plan for coverage, that the facility/providers are not required to provide a good faith estimate at this time. While we recognize that many facilities and providers may code these patients as "selfpay," the No Surprises Act law and regulations would not consider the patient to be self-pay if they intend to have the claim submitted to their plan for coverage.

20) **Is there a waiver that the patient would need to sign acknowledging the out-of-network status of the care and accepting the responsibility to pay the out of network difference?**

In some circumstances, yes. This is referred to as the notice and consent process, which may be used in limited circumstances when an out-of-network facility or provider wishes to balance bill a patient. We refer you to our Implementation Guide for more information on this process, including when it may be used.

21) **For scheduled services, will hospitals be required 1/1/2022 to know which network plans independent radiologists, pathologists, surgeons, etc. participate in when they bill their own professional fees so that the hospital can provide the required out-of-network notification?**

No. The law requires hospitals and other providers to give all patients with comprehensive commercial coverage a notice of their balance billing rights, regardless of the network status of any/all of the providers treating the patient. Please note that this is not the same notice as is required as part of the optional "notice and consent" process. If the out-of-network facility or providers wish to balance bill a patient using the notice and consent process they may need to provide the patients with information on alternative in-network options in some instances. More information on when these rules apply can be found in the regulations or in the AHA's Implementation Guide.

22) **Are hospitals required to include an estimate of the out-of-network provider's charges on the out-of-network notification?**

The first notice a provider must give a patient is a one-page notice of patients' balance billing rights. This is a generic notice provided to all patients covered by a comprehensive, commercial health plan and does not include any estimates.

If the out-of-network facility or provider want to balance bill the patient for out-of-network care, then they would need to use the notice and consent process, which must include a good faith estimate of charges. In instances of scheduled, non-emergent services, each out-of-network provider is responsible for seeking the patient's consent to waive their balance billing protections; however, facilities and providers may enter into agreements to have the facility manage this process for some or all providers.

23) **With regard to the specific timing on the notice and consent process, what is the time period for when the patient needs to consent to waiving their balancing billing protections and consent to be balance billed for the out-of-network care?**

The implementing regulations and guidance do not specify how far in advance of the service a patient must consent to balance billing. We interpret this to mean that consent must be obtained any time before care delivery begins, and note that the regulations do require a time stamp on when consent was obtained to ensure it was in advance of when care began.

Notification of Plans

1. **How do providers and facilities notify plans that patients have waived their balance billing protections?**

   The rules require that providers and facilities transmit the signed consent form. The Departments have not provided guidance regarding how this will be operationalized. Therefore, we suspect that transmission will likely be manual and/or use existing communication channels until standardized electronic methods can be developed.

2. **If an out-of-network facility does not plan to balance bill an outofnetwork patient, is notice and consent required? Does the facility have to notify the payer about the out-of-network care provided for which they do not intend to balance bill?**

   Notice and consent is not required if the provider is not seeking to obtain the patient's consent to balance bill. The government encourages (does not require) providers to alert the plan that the patient may be subject to the ban on balance billing when submitting a claim. While we understand it may be common for providers to alert plans in advance of billing that they are treating one of the plan's enrollees out-of-network, there is no requirement in the law or regulations to do so.

Language Accessibility

1. **What are the language access requirements for the forms used to provide a patient notice of out-of-network care and to seek the patient's consent to balance bill for that out-of-network care?**
   The implementing regulation require that the notice and consent forms be available in the top 15 languages of the state or geographic region. It is the responsibility of providers and facilities to have these forms translated and available. The AHA has requested that CMS assist facilities and providers by having these notice and consent forms translated in the top 15 languages in the U.S.

Record Retention

1) **If there is no statute of limitations for patients to raise potential violations of the No Surprises Act, how do providers address record retention going forward for the notice and consent documents, as well as supporting patient records?** The AHA is concerned that the absence of a statute of limitations and the current record retention policy of seven-years are not in alignment. We have asked the government to establish a five-year statute of limitations and a seven-year record retention policy.

Public Disclosure

What It Is: Providers and facilities also must make publicly available information on patients' rights with respect to balance billing. This public disclosure notice must be posted on the provider's public websites, and the regulations encourage providers and facilities to display the notice in publicly accessible locations, such as patient check-in, scheduling and billing locations. The information must contain the requirements established under the law, information on any state-level protections if applicable, and contact information for state and federal agencies to report any potential violations. In addition to posting the patients' rights information, providers and facilities must provide a one-page notice to patients. Patient notice must be received when the provider or facility asks for payment or submits a claim. To reduce administrative burden, the departments provided a model form on CMS' webpage that can be used. Facilities, per written agreement, can post the notice for their providers. In addition to the notice and consent forms, CMS provides a model disclosure form found here (CMS Form-10780 (available here). Providers and facilities that use this model form will be considered to be in good faith compliance with this disclosure requirement.

Effective Date: January 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021
  - Sec. 104. Health care provider requirements regarding surprise medical billing.
- **Regulations:** See the following sections of the Code of Federal Regulations, as discussed in the Interim Final Rule: Requirements Related to Surprise Billing; Part I
  - **ERISA:** 29 CFR Part 2590
  - **Individual and Fully Insured Markets:** 45 CFR 149.410(b)(2), 45 CFR 149.450(c)
  - **Federal Employee Health Benefit Plans:** 5 CFR 890.114
- **Other Federal Guidance:** N/A

Frequently Asked Questions

Public Disclosure of Patient's Balance Billing Protections

1) **Where can I find the disclosure requirements that facilities and providers must publicly display?**

   The CMS model disclosure form and instructions can be found here CMS-10780 | CMS. You will need to download and unzip the files.

2) **If state law also has notice and consent requirements, do the federal protections also have to be posted?**
   Yes. See the above link in FAQ E 1 for instructions.

3) **Does the one-page disclosure notification of patients balance billing protections have to be provided at each patient encounter?**

   We have recommended that the Departments allow the facilities and providers some flexibility and limit the dissemination of the one-page notice to, for example, the first encounter of a patient's episode of care.

4) **For the one-page notice facilities and provider must issue describing the patient balance billing protections, is that notice required to be given to every single patient walking into the hospital or only out-of-network patients?**

   The law and regulation requires that hospitals give the notice describing patient balance billing protections to all patients covered by insurance. Therefore, the conveyance of the notice is not limited to those that are out-of-network. The final rule stipulates that, at a minimum, providers and facilities should give the notice to the patient at the time of billing. However, the rule does offer providers and facilities some flexibility on the timing of the notice and gives an example that the notice could be conveyed to the patient at the time a procedure is scheduled. In our comments to the Departments, we recommended additional flexibility such that the facility or provider could provide the notice to a patient once during an episode of

treatment. See the above link in FAQ E 1 for information regarding the disclosure and notice model forms.

5) **Do providers/facilities need to give the one page notice to ALL patients, or just to patients who may be subject to out-of-network care that is eligible for protections?**

The guidance states that facilities and providers: "… *must give the disclosure notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, including covered individuals in a health benefits plan under the Federal Employees Health Benefits Program, and to whom they furnish items or services, and then only if such items or services are furnished at a health care facility, or in connection with a visit at a health care facility."*

In other words, and as described in response to question 4 above, facilities and providers must give the notice to all patients with comprehensive commercial coverage, regardless of network status. They do not need to provide the notice to uninsured/self-pay patients, or a patient enrolled in a public program, including through a Medicare Advantage or Medicaid managed care plan.

6) **Do hospitals have to track when the one-page disclosure is handed or mailed to the patient? For example, are hospitals required to track the distribution of the individual disclosure notice in the electronic medical record?**

There is no specific requirement to track when a disclosure notice if provided to a patient. However, the AHA recommends developing an approach to maintaining such records such that the hospital can audit to ensure compliance.

7) **Does the one-page notice about patient's balance billing rights also have to be translated into the top 15 languages like the notice and consent documents?**

No. There is no requirement that the one-page notice, nor the information posted on the hospital's website or in the common areas informing patients of their balance billing rights, be translated into the top 15 languages. However, CMS provides the following information language access resources and information on compliance with federal civil rights laws. (See link CMS-10780 | CMS.)

Use of Plain Language: *Health care providers, facilities, plans, and issuers are encouraged to use plain language in the disclosure notice and test the notice for clarity and usability when possible.*

Plain language, accessibility, and language access resources:

- *Federal plain language guidelines | plainlanguage.gov*
- *Section508.gov Accessibility Requirements Tool*
- *Limited English Proficiency Welcome to LEP.gov*

Compliance with Federal Civil Rights Laws: *Entities that receive federal financial assistance must comply with federal civil rights laws that prohibit discrimination. These laws include section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, and section 504 of the Rehabilitation Act of 1973. Section 1557 and title VI require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include offering language assistance services such as translation of written content into languages other than English.*

8) **If a patient is seen via telehealth, what is the process for providing the documents to the patient and making sure the patient receives it?**

   The regulations do not address a specific process for telehealth patients. However, it may be a good practice to ensure that the public disclosure notice is conveyed to the patient in both mail and electronic form and that conveyance of the form is documented in the patient's record.

9) **Do facilities and providers need to provide the one-page notice to Medicare and Medicaid patients, including Medicare Advantage and Medicaid managed care patients?**

   No. The No Surprises Act prohibition on balance billing does not apply to those programs, regardless of whether the patient is enrolled in a Medicare Advantage or Medicaid managed care plan to receive their benefits. Patients in these programs are already protected from balance billing through other policies.

Continuity of Care

What It Is: This section of the law provides for continuity of services for enrollees of health plans when there is a change in the plans' provider network. These protections extend to individuals defined as a "continuing care patient" and include patients who are undergoing a course of treatment for a serious or complex condition; undergoing institutional or inpatient care; scheduled to undergo non-elective surgery including postoperative care; pregnant and undergoing treatment; or terminally ill and receiving services. Plans are required to ensure continuing care patients receive timely notification of changes in the network status of providers and facilities. Such patients will have up to 90 days of continued coverage at in-network cost sharing to allow for a transition of care to an in-network provider.

Effective Date: January 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the

Consolidated Appropriations Act, 2021 ○ Sec. 113. Ensuring continuity of care.

- **Regulations:** N/A
- **Other Federal Guidance:**
  - ○ FAQs regarding timing for additional guidance on continuity of care provision

Frequently Asked Questions

1) **Will these provisions go into effect on January 1, 2022?** Yes. According to the Departments' FAQs, these provisions will go into effect on January 1, 2022. However, the Departments will be unable to provide additional guidance to providers and plans by that time. Pending further guidance, the Departments ask providers and plans to use their best judgement in implementing these provisions.

2) **A specialist in our health system saw a patient once but did not begin a course of treatment. Does this patient qualify as a "continuing care patient?"** Absent additional federal guidance, we encourage providers to use their best judgement in determining which patients qualify as continuing care patients. We understand, for example, that many plan/provider contracts include provisions regarding continuity of care. We believe such provisions are a reasonable starting point to help determine who may qualify as a "continuing care patient" under these provisions.

3) **My organization is treating a continuing care patient. However, the insurer now refuses to respond to any communications, such as prior authorizations. What do we do?** Absent additional federal guidance, we encourage providers to report such instances through the single complaint process that is being established for purposes of reporting violations of the No Surprises Act. We will provide more information on this process as it becomes available.

Provider Directories

What It Is: Beginning for health plan years on or after Jan. 1, 2022, plans will be required to establish a verification process to ensure accurate provider directories, a response protocol for individuals inquiring about the network status of a provider, and a publicly accessible provider database. These provider directory requirements do not pre-empt existing state law, and patients that relied on inaccurate provider directory information would only be subject to the in-network cost sharing amounts. The law requires that health plans verify and update provider directory information no less than every 90 days (or within two days of receiving notice of a change), as well as establish a procedure for removal of providers who are no longer in network. Plans are required to respond to individuals inquiring about the network status of a provider or facility within one business day of the inquiry and must retain records of the inquiry for two years. Plans must have a web-based provider directory that includes the provider and facility contact information, specialty information, direct or indirect contractual relationship with

the plan, and digital contact information. Health plans also will be required to make information available on their websites and through other plan communications regarding balance-billing protections. Such information also must include the appropriate federal and state contact information for consumers to report any violations. Plans also are required, where state law applies, to provide information regarding allowable charges by non-contracting providers or facilities and any consumer cost-sharing obligations.

Effective Date: January 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021
  - Sec. 116. Protecting patients and improving the accuracy of provider directory information.
- **Regulations:** N/A
- **Other Federal Guidance:**
  - FAQs regarding timing for additional guidance on provider directory provision

Frequently Asked Questions

1) **Will these provisions go into effect on January 1, 2022?** Yes. According to the Departments' FAQs, these provisions will go into effect on January 1, 2022. However, the Departments will be unable to provide additional guidance to providers and plans by that time and therefore anticipate exercising enforcement discretion. The Departments indicate that plans will not be deemed out of compliance so long as they impose a cost-sharing amount that is not greater than the cost-sharing amount that would be imposed for items and services furnished by a participating provider. Pending further guidance, the Departments ask providers and plans to use their best judgement in implementing these provisions.

2) **The health plan terminated our contract. Do we have any responsibilities with respect to updating the provider directory?** At this point, we do not believe providers have any additional responsibilities as a result of the No Surprises Act. However, we encourage providers to raise with the health plan for which they plan to contract with the issue of updating the provider directory as part of the termination process for the contract.

3) **We assessed the cost-sharing consistence with the remittance from the plan. Do we still owe a rebate to the consumer, including with interest?** Pending further guidance, we do believe that providers are responsible for returning any excess cost-sharing collected to the consumer with interest.

Uninsured/Self-Pay Good Faith Estimates

What It Is: Providers will be required to provide uninsured and self-pay patients *good faith estimates* of expected charges for all scheduled services prior to care and upon request when shopping for care. To ensure that patients receive one document with clear and understandable information on their expected costs, HHS establishes a process for one provider or facility ("convening provider/facility") to coordinate and deliver the good faith estimates of all expected charges across all providers and facilities involved in the anticipated course of care. While the requirements go into effect on Jan. 1, 2022, HHS plans to exercise enforcement discretion through Dec. 31, 2022, as it relates to incorporating the good faith estimates from outside providers or facilities and encourages states to do the same.

Key Definitions:

- Convening Provider or Facility. HHS defines "convening health care provider or facility" as the provider or facility that is responsible for scheduling the primary item or service or that receives the request for a good faith estimate. The convening provider or facility is responsible for notifying the uninsured or self-pay patient about the good faith estimates, coordinating the estimates from all providers, and delivering the combined good faith estimate to the patient.
- Co-provider or Facility. HHS defines "co-health care providers or facilities" as facilities or providers other than the convening provider or facility that typically provide care in conjunction with the primary item or service.
- Expected Charge. For purposes of providing good faith estimates to uninsured or self-pay patients, HHS defines "expected charge" as the cash pay rate or rate for an uninsured or self-pay patient, reflective of any discounts available for the individual patient (e.g., financial assistance policies). HHS notes that this is likely different than the "expected charge" for an insured patient's good faith estimate, which CMS anticipates will be the undiscounted gross charge or chargemaster rate.
- Items and Services. HHS defines "items and services" as all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment and fees (including facility fees) provided or assessed in connection with the provision of health care.
- Primary Item or Service. HHS defines the "primary item or service" as the item or service that is the initial reason for the visit and is provided by the convening provider or facility.
- Period of Care. HHS defines "period of care" as the time during which the primary service and all related items and services that would not be scheduled separately are provided. HHS provides the example of a knee surgery, noting that the period of care covered by the good faith estimate would include all of the services associated with the surgery from admission to discharge, including the

physician professional services, assistant surgeon professional services, anesthesiologist professional services, facility services, prescription drugs, and any durable medical equipment used. It would not include any pre- or post-procedure care that would typically be scheduled separately, such as preoperative consultation or post-operative physical therapy.

- Uninsured or Self-pay Individual. HHS defines an "uninsured or self-pay" patient as an individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, federal health care program, or a health benefits plan OR an individual who is choosing to not use their coverage benefit. Note that this definition includes individuals enrolled in short-term, limited duration health plans, as well as those individuals in other types of products that are not regulated as health insurance coverage, such as individuals in health sharing ministries.

Coordination and Delivery of the Good Faith Estimate: The process HHS establishes for the good faith estimates is as follows. First, the convening provider or facility must alert uninsured or self-pay patients shopping for or scheduling services about their rights to a good faith estimate of expected charges, both orally and in writing. Notices must be displayed prominently in a provider's office wherever scheduling occurs, as well as on the provider's website, and be easily searchable from a public search engine. HHS provides a model notice for notifying uninsured or self-pay patients of these rights here.

Once an item or service has been scheduled with at least three days between scheduling and service delivery, or an uninsured or self-pay patient inquiries about expected costs for an item or service, the convening provider has no more than one business day to request good faith estimates from all co-health care providers and facilities and one to three days to deliver the good faith estimate to the patient (see timeline below). Should the information in the good faith estimate change between when the initial estimate was provided and the scheduled item or service is delivered (e.g., there is a change from one provider to another), the convening provider or facility is responsible for reissuing the good faith estimate no later than one business day before the item or service is scheduled to be provided. If a change in staffing occurs less than one business day in advance, the replacement provider or facility must accept the initial good faith estimate that was provided by the original provider or facility.

HHS notes that for uninsured patients that request a good faith estimate in advance of scheduling and ultimately do schedule the item or service, the convening provider will need to issue a new good faith estimate upon scheduling. In addition, the regulations permit one good faith estimate for recurring items or services, but the good faith estimate must be redone after a 12-month period. In any instance when the good faith estimates change, HHS requires the provider or facility to explain the changes to the patient.

Timeline:

Scheduled services <3 days out	Not required
Scheduled services 3-9 days out	Convening provider/facility must coordinate with the co-providers/facilities and deliver the comprehensive good faith estimate no later than **1 business day** after the date of scheduling
Scheduled services 10+ days out OR when shopping for care prior to scheduling	Convening provider/facility must coordinate with the co-providers/facilities and deliver the comprehensive good faith estimate no later than **3 business day** after the date of scheduling

Note: Good faith estimates are also required as part of the notice and consent process related to balance billing out-of-network patients. In the case of the notice and consent process, good faith estimates may be required for same-day services.

Content of Good Faith Estimate: The uninsured or self-pay good faith estimates need to include the following content:

- The patient's name and date of birth;
- A description of the primary item or service;
- An itemized list of other items or services reasonably expected to be provided with the primary item or service during the period of care grouped by each provider/facility;
- Applicable diagnosis and expected service codes[1], with expected charges listed with each item/service;
- The name, National Provider Identifier (NPI), and Taxpayer Identification Number (TIN) of each provider/facility included in the good faith estimate, and the state(s) and location where the items/services are expected to be furnished;
- A list of items/services the convening provider anticipates will require separate scheduling, before or after the primary service (e.g., physical therapy), including a disclaimer directly above the list that states that separate good faith estimates will be issued to the patient upon scheduling or request; and
- Several disclaimers, including one alerting the patient to their right to initiate a patient-provider dispute resolution process if the billed charges are "substantially in excess" of the good faith estimates.

The items and services in the good faith estimate are required to be itemized and clearly grouped by their respective provider or facility. In addition to each individual charge, the estimate must include a total charge for each provider or facility. The total charge for the provider or facility is the amount that can be contested through the patient-provider

[1] HHS notes that facilities or providers should use the most comprehensive service code available. In other words, if a single service code captures multiple components of an item or service that is the service code and corresponding charge that should be used.

dispute resolution process (see below), if the total billed charge exceeds the expected total charge by $400 or more. A template good faith estimate can be found here.

Method for Providing the Good Faith Estimate: HHS requires providers to transmit the estimate in written form, either on paper or electronically (e.g., through a patient portal), based on the patient's preference. If shared electronically, the estimate must be able to be saved and printed. HHS requires the estimate to be written in clear and understandable language, and "in a manner calculated to be understood by the average uninsured or self-pay individual." Nothing in the rule precludes a provider from discussing the contents of the estimate with a patient but delivering the information verbally only would not meet this requirement.

Effective Date:

- Convening provider/facility good faith estimates for **uninsured/self-pay** patients → January 1, 2022
- Comprehensive good faith estimates for **uninsured/self-pay** patients (inclusive of co-providers/facilities' charges) → January 1, 2023

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021 ○ Sec. 112. Patient protections through transparency and patient-provider dispute resolution
- **Regulations:** See the following sections of the Code of Federal Regulations, as discussed in the Interim Final Rule: Requirements Related to Surprise Billing; Part II
  - **Individual and Fully Insured Markets:** 45 CFR 149.610 **Other Federal Guidance:**
  - Model notices and information collection requirements for the good-faith estimate and patient-provider payment dispute resolution

Frequently Asked Questions

1. **When do facilities and providers need to begin providing good faith estimates for patients scheduling or shopping for care?** Providers and facilities are required to provide ***uninsured or self-pay*** patients with good faith estimates for scheduled services (or upon request) beginning Jan. 1, 2022. The government has delayed implementation of the good faith estimates for ***insured*** patients until further rulemaking. AHA is seeking clarity from HHS on whether items/services scheduled in 2021 for a 2022 date require good faith estimates and, if yes, when such estimates would be due.

2. **Isn't the government delaying enforcement of these requirements?** In part. The government will delay enforcement of two components of the good faith estimates

policies: 1) the requirement that the convening provider collect all components of an estimate from co-providers when providing a good faith estimate to an **uninsured or self-pay** patient, and 2) the requirement to provide good faith estimates for **insured** patients for use in the health plans' advanced explanations of benefits (AEOBs).

3. **Do these policies apply to all scheduled services?** Yes, this requirement applies to all scheduled services for patients who are uninsured, do not have coverage for the scheduled item/service, or do not plan to submit a claim for the scheduled item/service to their health plan, i.e., self-pay. In other words, providers and facilities are required to provide an estimate when: (i) a service is scheduled; (ii) a request for a good faith estimate has been made; or (iii) an inquiry as to the potential cost of a service or item has been made.

4. **How are the good faith estimates for uninsured and self-pay patients calculated?** The good faith estimates need to be the cash/self-pay rates, reflective of any discounts (e.g., financial aid) for which the patient would be eligible, even if the discount brings the patient's expected bill to $0. A patient- centered approach is advised when screening for financial assistance.

5. **Does this policy require a provider or facility to screen all uninsured or selfpay patients for financial assistance eligibility prior to scheduling?** Good faith estimates are expected to reflect financial assistance. The AHA and HFMA are seeking further clarification from the Department of Health and Human Services (HHS) on whether need-based financial assistance screening must occur for all patients prior to the issuance of a good faith estimate or whether providers can instead limit proactive financial assistance eligibility assessments only to patients who request one or those for which the hospital has a reasonable expectation of eligibility.

6. **What disclosures are required on the good faith estimate?** The convening provider must include the following types of disclosures on the good faith estimate:
    - a disclaimer informing the patient that there may be other items or services recommended by the convening or co-provider as part of the course of care that need to be scheduled separately; and
    - a disclaimer noting that the expected charges listed are only estimates and that the final billed charges may differ; and
    - a disclaimer on the patient's right to the patient-provider dispute resolution process, including information on how to initiate the process; and

- a disclaimer that the estimate is not a contract and does not require the patient to obtain the items or services listed on the estimate. (This disclaimer is also required of all the co-providers and co-facilities.)

7. **Is there model language for the notification of rights and good faith estimate disclosures?** Yes. HHS provides model language for informing uninsured/self-pay patients of their right to good faith estimates and the patient- provider dispute resolution process; HHS provides a template of the comprehensive good faith estimate with model disclaimer language here.

8. **Are patients required to sign the good faith estimates to prove they received them?** No, the patients do not need to sign or otherwise verify that they received the good faith estimate.

9. **How does HHS define "self-pay?"** HHS defines "self-pay" patients as patients who may have health care coverage but do not have benefits for an item or service under the health plan *or* do not plan to submit a claim to their insurance for the scheduled item or service. If the patient does ultimately submit a claim for the item or service, they are no longer considered self-pay and are not eligible for the patient-provider dispute resolution process.

10. **What is the required method of delivery of the good faith estimate to the uninsured/self-pay patient?** The good faith estimates need to be delivered either electronically (e.g., secure email, patient portal message) or via paper mail, based on the patient's preference. If the estimates are delivered electronically, they must be provided in a manner that allows the patient to save and print the estimate.

11. **What items/services need to be included in the good faith estimate?** Good faith estimates need to include all items/services expected to be delivered during a period of care. In other words, good faith estimates should include the primary service (e.g., knee surgery), as well as all the items/services associated with the primary service that wouldn't be scheduled separately (e.g., physician professional services, anesthesiologist professional services, facility services, prescription drugs). The estimate does not need to include pre- or post-service estimates for items/services that would typically be scheduled separately (e.g., physical therapy), though the convening provider must include a list of typical pre- and post-service items or services on a good faith estimate.

12. **Does this requirement apply only to facility-based care?** No, this requirement applies to all services in any setting (e.g., hospital, clinic, urgent care) that are

scheduled 3+ days in advance. This includes pre-paid, elective services (e.g., elective cosmetics).

13. **Do these requirements apply to out-of-network patients?** These requirements only apply to out-of-network patients if the patient does not plan to have a claim for coverage submitted to their insurance. If the patient does plan to have an out-ofnetwork claim submitted to their insurance, then these requirements do not apply.

14. **How do these good faith estimates relate to the notice and consent estimates?** These good faith estimates must be provided to any *uninsured or selfpay patient prior to any scheduled item or service*. The notice and consent estimates are required specifically when an out-of-network provider or facility seeks to balance bill certain *insured out-of-network* patients for scheduled or post-stabilization care, consistent with other requirements in the No Surprises Act. As noted above, there may be some instances in which an out-of-network patient may seek care as a selfpay patient. In those instances, the good faith estimate requirements apply and not the notice and consent requirements.

15. **HHS defines the convening provider as the provider/facility responsible for scheduling the primary item/service or that receives the request for an estimate. In practicality, does this mean the convening provider is the physician who requests a procedure to be scheduled at a hospital or the hospital that schedules it?** The regulations are not clear on this point. The AHA is seeking clarity from HHS.

16. **Can the convening provider simply utilize the required machine-readable files posted on each hospital's website (as required under the Hospital Price Transparency rule) to gather the co-facility estimate information?** No. The good faith estimates need to be the cash/self-pay rates, reflective of any discounts (e.g., financial aid) for which the patient would be eligible. The machine-readable files include general rates and would not allow a convening provider to derive a patient-specific estimate.

17. **How quickly does the co-provider or co-facility need to return expected charges and additional information to the convening provider?** The regulation allows the convening provider or facility to set a deadline for co- providers/co-facilities such that they can meet the deadline for returning the good faith estimate to the patient. The deadline must be included in the request for expected charges that the convening provider or facility sends to the co- providers/co-facilities. The co-provider’s response also must include the patient’s name and date of birth; an itemized list of expected items and services to be provided by the co-provider;

applicable diagnosis and service codes; the co- provider's name, NPI, and TIN; and a disclaimer that the good faith estimate is not a contract.

18. **How quickly does the convening provider or facility need to return the consolidated good faith estimate to the patient?** The convening provider or facility must provide a consolidated good faith estimate of expected charges for all items and services to an uninsured or self-pay patient within the following timeframes:
    - if a service is scheduled at least 3 days in advance, the good faith estimate must be provided no later than 1 business day after the date of scheduling; or
    - if a service is scheduled at least 10 days in advance, the good faith estimate must be provided no later than 3 business days after the date of scheduling; or
    - if an estimate of expected costs is otherwise requested by an uninsured or self-pay individual, the good faith estimate must be provided no later than 3 business days after the request.

19. **Is the co-provider/co-facility any provider or facility outside of the convening provider/facility?** A co-provider/co-facility is any provider or facility that will provide care for the patient as part of a scheduled service for whom the convening provider does not bill. In other words, co-providers/co-facilities are the other providers/facilities delivering items/services during the period of care covered by the good faith estimate that would bill separately from the hospital.

20. **Do these policies apply to patients with short-term, limited-duration plans, liability insurance/workers compensation plans, or health sharing ministries?** Patients enrolled in these types of coverage, absent enrollment in other forms of comprehensive coverage, are considered uninsured for the purpose of this regulation, as these types of coverage are not recognized as group health insurance. Therefore, these patients should receive uninsured/self- pay good faith estimates prior to scheduled care.

21. **Do these policies apply to reference-based pricing plans?** Reference-based pricing plans that are offered as part of ERISA-regulated group health insurance are subject to these regulations. Therefore, patients with reference-based pricing plans are considered insured, and therefore do not need to receive an uninsured/self-pay good faith estimate for scheduled services.

22. **Do these policies apply to federal health care programs coverage?** Items and services covered under a federal health care program, such as Medicare, Medicaid, Indian Health Service, or Tricare are considered insured. Therefore, unless they

have otherwise indicated a desire to self-pay, these patients do not need to receive an uninsured/self-pay good faith estimate for scheduled services.

23. **If a patient that requested a good faith estimate goes on to schedule a procedure, does the provider need to provide a new good faith estimate?** Yes, if the patient schedules the service following a request for a good faith estimate, a new estimate is required.

24. **What content is required to be included on the good faith estimate in instances when the final code is unknown at the time of scheduling (e.g., E&M CPT codes, Dx codes) Would a standard menu of all possible codes and their corresponding charges suffice?** Providers should use their best efforts to provide a good faith estimate that is reflective of what the final bill will include. Though additional services that are unknown at the time of scheduling are often unavoidable and to be expected, the regulation leaves additional costs exceeding $400 from the good faith estimate (including additional, unexpected services) to be subject to the patient dispute resolution processes. We recommend that providers develop a policy on how to handle additional services in advance of Jan. 1, 2022. We also recommend that providers adjust their processes to ensure that good faith estimates are properly created by people with knowledge of billing processes. Additional training for front office and finance staff will likely be required in order to achieve compliance with the regulation.

25. **Are insured patients that do not have coverage for a particular item or service considered uninsured for the purpose of this requirement?** Yes, patients that are not covered for a particular item or service are considered uninsured for the purpose of these requirements. The AHA and HFMA are seeking further clarification from HHS on how providers should proceed when determining an insured patient's coverage for an item or service is not feasible in the short good faith estimate timeline.

26. **Is it still acceptable to require a point of service collection for a self-pay scheduled service?** There is nothing in this regulation that would prevent a provider from requiring point of service payments from a patient. However, if the point of service collection is associated with any type of prompt pay discount, the good faith estimate should reflect the discounted amount.

27. **Are there penalties for non-compliance with these requirements?** If a provider does not comply with these requirements and the uninsured/self-pay patient's bill is over $400, then the patient can initiate a patient-provider dispute resolution process. In addition, any provider or facility found to be in violation of the new requirements established under the No Surprises Act (including the good faith estimates for insured or uninsured patients, once they are both in effect) could be subject to

penalties under state and federal law, including civil monetary penalties. (*Citation: Section 2799B-4*)

28. **How long do providers need to store the good faith estimates?** The good faith estimates are considered part of a patient's medical record and should be stored in the same manner as other items in the patient's medical record. The convening provider must be able to provide a patient a copy of any previously issued good faith estimate furnished within the previous six years.

29. **Can providers give patients one good faith estimate for a series of visits?** Yes, for recurring items or services, providers/facilities can deliver patients a single good faith estimate, as long as the estimate clearly identifies the scope of the estimate (e.g., timeframe, frequency, total number of visits). In addition, the good faith estimate would need to be updated annually and/or whenever there is a change to the estimated charges or scope.

30. **Do the good faith estimates need to include line item estimates, or can they be bundled under one code?** HHS is clear in the regulation that facilities or providers should use the most comprehensive service code available. In other words, if a single service code captures multiple components of an item or service that is the service code and corresponding charge that should be used. In instances when a comprehensive code is used, the comprehensive service code should be used for billing purposes as well.

31. **Are providers/facilities required to provide patients good faith estimates for same day services or for services scheduled less than 3 days in advance?** No, good faith estimates are only required for services scheduled at least 3 days in advance.

32. **What should providers/facilities do about unexpected additional services during a scheduled health care visit, such as consultation with an outside provider?** Providers should include charges for all services for which they are aware at the time of scheduling. To the extent that additional medically necessary services are performed, providers may charge for these services, though such charges would potentially be subject to a patient dispute resolution process if in excess of $400. We recommend that providers create policies to prepare for such scenarios.

33. **Can patients decline the good faith estimates at the time that they are notified of their rights to receive the good faith estimates?** No, patients are not required to sign good faith estimates, so therefore, cannot decline them. In other words, facilities/providers are always required to give uninsured/self-pay patients good faith

estimates for services scheduled 3+ days in advance and whenever requested during the shopping process.

34. **Are retail services, such as acupuncture, included in these requirements?** Yes, good faith estimates are required for all items/services scheduled by an uninsured or self-pay patient 3+ days in advance or by request when shopping for care. HHS defines *items and services* very broadly to mean "all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care." In the regulation, HHS notes that this definition is inclusive of those items and services related to dental health, vision, substance use disorders and mental health.

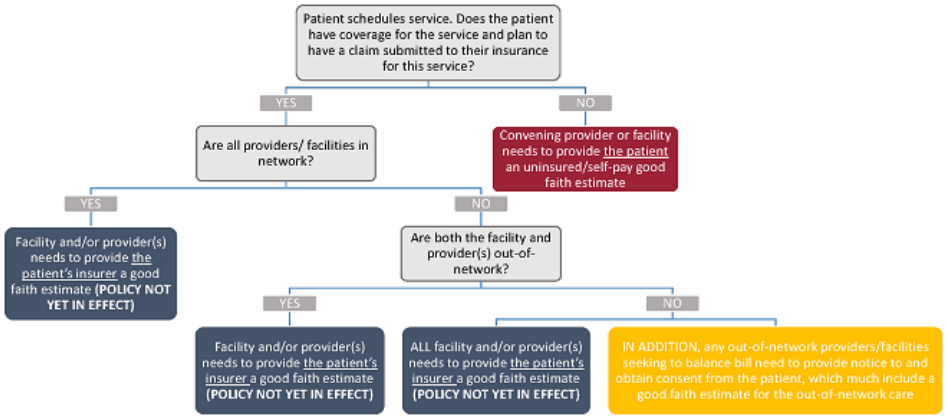
35. **If a patient presents with insurance for a scheduled procedure but at a future date we find out that the insurance retroactively terminated and the patient is deemed self-pay/no-insurance at that time, how should the provider/facility proceed given that no good faith estimate would have been generated at admission?** If a provider learns that a scheduled patient's insurance has been retroactively terminated prior to the provision of care, they should provide the patient with a good faith estimate upon learning. The regulation is unclear as to how providers that learn of a patient's lapse in coverage after care is provided should proceed when a good faith estimate was not produced due to a prior indication that the patient was insured. We recommend that providers review their eligibility batching process to assure payer coverage is validated 3 days prior to scheduled services to minimize surprises. The AHA/HFMA have requested clarification on this issue from CMS and will provide an update once we have additional information.

When Do Good Faith Estimates Apply to Emergency Services, including Post-stabilization Services?

Good faith estimates are not required for emergency services up to the point of stabilization (as defined by EMTALA). However, they may be required for care provided post-stabilization as part of the notice and consent process, if the provider is eligible to seek the patient's consent to balance bill.

American Hospital Association
Advancing Health in America

When Must a Provider Give a Good Faith Estimate for a Scheduled Service?



American Hospital Association
Advancing Health in America

Patient-Provider Dispute Resolution Process

What It Is: The patient-provider dispute resolution process allows uninsured/self-pay patients an avenue for contesting a bill when the billed charges are "substantially in excess" of the good faith estimates provided prior to care.

Definition of "Substantially in Excess": The regulations define the term "substantially in excess" to mean a total billed amount for a specific provider or facility that is at least $400 more than the total amount of expected charges as listed on the uninsured or self-

pay patient's good faith estimate. In other words, each provider or facility listed on the good faith estimate could be subject to a patient-provider dispute resolution process if that provider or facility's total billed amount for all items and services provided by that provider is $400 or more than that provider's total estimated amount.

Eligibility for the Patient-Provider Dispute Resolution Process: Uninsured patients that receive a bill from a provider or facility totaling $400 or more than the good faith estimate of charges are eligible to initiate the patient-provider dispute resolution process. HHS notes that the items on the bill do not need to have been included on the good faith estimate for them to count toward the total billed charge. For example, if a provider provided a good faith estimate for services A ($100) and B ($50), the total estimated charge would be $150. If the provider ended up furnishing services A ($200), B ($50), and C ($350), the total billed charges would be $600 and the patient would be eligible to initiate the dispute resolution process.

It is important to note that while the convening provider (defined in the previous section) is responsible for coordination and delivery of the estimates, each individual provider/facility is responsible for the accuracy of their own estimates. In addition, if a co-provider or co-facility (defined in the previous section) is replaced and a new good faith estimate is not rendered, the new co-provider or co-facility must accept the original co-provider or co-facility's good faith estimate. If the new provider bills charges that are in excess of $400 of the original provider or facility's estimates, the patient could initiate the dispute resolution process against the new provider.

Because HHS plans to exercise enforcement discretion for one year regarding the inclusion of co-provider and co-facility estimates as part of the good faith estimate, many good faith estimates will not include estimates for co-providers or co-facilities in 2022, or they will include a range (as encouraged by HHS). During this time, items and services provided by co-providers and co-facilities that do not have pre-service estimates are not eligible for the dispute resolution process. However, patients are encouraged to separately ask co-providers or co-facilities for estimates, and if patients follow this process, such providers could face the dispute resolution process.

Patient-Provider Dispute Resolution Process: A patient must initiate the patient-provider dispute resolution process within 120 calendar days of receiving the initial bill containing charges in excess of $400 of the provider or facility's total expected charge. The initiation notice can be submitted through the Federal IDR Portal, electronically, or on paper. To initiate the process, the patient also must pay an administrative fee. If the patient ultimately prevails in the dispute resolution process, the SDR entity will reduce the final payment amount by the initial fee paid by the patient. If the patient and provider settle before the dispute resolution process, the provider or facility must reduce the settlement amount by at least half of the administrative fee.

Once the process is initiated, HHS will select the SDR entity. HHS plans to only certify enough SDR entities to provide timely resolution of patient-provider disputes; in the first year, HHS anticipate contracting with 1-3 certified SDR entities. SDR entities will be

evaluated based on whether they meet certain applicable certification requirements, which are separate and apart from the IDR certification requirements. The SDR entities will need to comply with all of the IDR confidentiality requirements and the same language access requirements as the IDR entities. Unlike the IDR entities though, the SDR entities will need to show that they are able to operate nationwide, and they must submit a conflict-of-interest mitigation policy.

HHS will choose an SDR entity for a particular case on a round robin basis, skipping over an SDR entity that is identified to have a conflict of interest. After the SDR entity has been selected, it will notify the uninsured or self-pay patient and the provider or facility that a dispute resolution request has been received and is under review. **While the process is pending, the provider or facility cannot move bills for the disputed items or services into collections or threaten to do so, and if the bill is already in collections, the provider or facility should cease any collections efforts. Similarly, the provider or facility must suspend the accrual of any late fees during this process, as well as not take or threaten to take any action against the patient for utilizing the dispute resolution process.**

After reviewing the initial request, the SDR entity will notify the patient with the outcome of the review. If the review determines the case to be incomplete or ineligible for the process, the patient will have 21 calendar days to submit any missing or supplemental information to make their case. If the SDR entity determines a case is eligible for the process, it will notify both parties and request information from the provider or facility within 10 business days. The provider must include the following in response:

- A copy of the good faith estimate;
- A copy of the billed charges; and
- Documentation showing that the difference between the estimate and billed charges are the result of “a medically necessary item or service based on an unforeseen circumstance that could not have reasonably been reasonably anticipated.”

No later than 30 days after the provider or facility submits the information, the SDR entity must make a determination on the amount to be paid by the patient. Any time during the process, the patient and provider can settle on a payment amount, ending the dispute resolution process. In the case of a settlement, the provider or facility must notify the SDR no later than three days after the settlement, and include in the notice the settlement amount, date the settlement was reached, and documentation proving that all parties agree to the settlement.

Determination Amount: The SDR entity determines a payment amount for each item/service in question for a particular facility or provider and patient’s final total payment amount is determined by adding up each individual amount. The final payment amount is binding. The individual amounts are determined using the following methodology.

Determination	Payment amount
Change **is not** the result of a medically necessary change in the course of care and the item/service in question was included on the good faith estimate	Estimate Amount
Change **is not** the result of a medically necessary change in the course of care and the item/service in question was not included on the good faith estimate	$0
Change **is** the result of a medically necessary change in the course of care based on an appropriately unanticipated circumstance	Lesser of: - Total billed charge - median payment amount for the same or similar service in the geographic area that is reflected in an independent database

Effective Date:

- Patient-provider Dispute Resolution → January 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021 ○ Sec. 112. Patient protections through transparency and patient-provider dispute resolution
- **Regulations:** See the following sections of the Code of Federal Regulations, as discussed in the Interim Final Rule: Requirements Related to Surprise Billing; Part II
  - **Individual and Fully Insured Markets:** 45 CFR 149.620
- **Other Federal Guidance:**
  - Model notices and information collection requirements for the good-faith estimate and patient-provider payment dispute resolution

Frequently Asked Questions: *See section above*

Insured Good Faith Estimates/Advanced Explanation of Benefits

What It Is: Providers will be required to provide *good faith estimates* of expected charges for all scheduled services prior to care and upon request when shopping for care. For insured patients, the providers will transmit the good faith estimates to the patient's health plan; the health plan will use that information to create an advanced explanation of benefits (AEOB) for the patient.

Timeline:

Scheduled services <3 days out	Not required
Scheduled services 3-9 days out	provider must provide the good faith estimate no later than **1 business day** after the date of scheduling
Scheduled services 10+ days out OR when shopping for care prior to scheduling	provider must provide the good faith estimate no later than **3 business day** after the date of scheduling

Note: Good faith estimates are also required as part of the notice and consent process related to balance billing out-of-network patients. In the case of the notice and consent process, good faith estimates may be required for same-day services.

Effective Date:

- Good faith estimates for **insured** patients, AEOBs → TBD

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021 ○ Sec. 111. Consumer protections through health plan requirement for fair and honest advance cost estimate.
  - Sec. 112. Patient protections through transparency and patient-provider dispute resolution
- **Regulations: N/A**
- **Other Federal Guidance:**
  - FAQs delaying enforcement for insured estimates, advanced EOBs

Frequently Asked Questions

1) **Is the government delaying enforcement of these requirements?** The government is delaying enforcement of the good faith estimates for **insured** patients and the advanced EOBs. Providers will still be required to provide **uninsured** patients with good faith estimates for scheduled services beginning January 1, 2022.

2) **What happens if a provider does not provide the good faith estimates?** Any provider or facility found to be in violation of this requirement could be subject to penalties under state and federal law, including civil monetary penalties. *(Citation: Section 2799B-4)*

3) **How should providers send the good faith estimates for insured patients to the patient's health plans?** According to the FAQs delaying this requirement, technical standards will be developed for the transmission of these estimates prior to implementation of this requirement.

4) **How do these requirements interact with the notice and consent requirements for balance billing?** In some limited instances, an out-of-network facility or provider may seek to obtain the patient's consent to balance bill. In those cases, the facility or provider is required to follow the notice and consent process established by the Departments. The notice must include a good faith estimate of expected charges, and the facility/provider must calculate the estimate in the same way it would under this provision. Additional guidance on how to calculate the good faith estimates is anticipated in future guidance, but the Part II regulations provide commentary noting that the estimates are likely to be reflective of the amount that would be billed to a plan or issuer (i.e., undiscounted gross charge or chargemaster rate).

Oversight and Enforcement

What It Is: The states have primary enforcement authority over the requirements established under the No Surprises Act, though a process exists for CMS to become the enforcement authority should states fail to enforce or defer enforcement to the federal government. This process aligns closely to the current enforcement framework for plan requirements under the Public Health Service (PHS) Act, but is expanded to include provider/facility requirements as well. Enforcement will be based on complaints, reports, or audits (random or targeted). To track complaints, the federal government will run a unified complaint process and will then share the complaints with the proper enforcement authority. Additional details on each step of this process follow.

State vs. Federal Authority. States have primary enforcement authority over plans/issuers and providers/facilities with respect to the requirements under the No Surprises Act. However, in some instances, these responsibilities may transfer to the federal government, such as when a state notifies CMS that it has not enacted legislation or otherwise taken steps to enforce, or the federal government determines that the state is failing to enforce, the requirements. In such instances, CMS becomes the enforcement authority.

Complaint Process. The Interim Final Rule (Part 1) establishes a process through which the departments can collectively receive complaints about potential violations of all of the consumer protection and balance billing requirements included in the No Surprises Act. The single complaint process will apply to health plans, providers, facilities, and providers of air ambulance services. The process will allow for complaints to be made orally or in writing, and the departments will have 60 days to respond to the complaint. At a minimum, complaints will need to include sufficient information to identify the parties involved and the action/inaction subject to the complaint. As part of their process, the departments may seek additional information from any of the stakeholders involved, including the person submitting the complaint, the health plan or the provider/facility. In their response, the departments will need to detail next steps for the complaint resolution, which may include referring the complaint to another state or

federal resolution process, referring the complaint to the state or federal authority with enforcement jurisdiction, or initiating an investigation for enforcement action. There will be no statute of limitations on the timeframe for submitting a complaint.

Investigation Process. In instances when the federal government is the enforcement authority, HHS proposed an investigation process for providers/facilities that aligns closely to the process already established for plans/issuers under the PHS Act. HHS proposes that CMS may conduct an investigation of a provider/facility based on any information that indicates potential noncompliance, such as consumer or other complaints, reports from state insurance departments or the National Association of Insurance Commissioners (NAIC), or reports from other federal or state agencies. HHS also proposes to allow CMS to conduct random or targeted investigations.

Enforcement Process. HHS proposes that, upon identifying a potential violation, CMS would provide written notice to the provider or facility describing the information that prompted the investigation, if applicable. The notice also would state that a civil monetary penalty (CMP) may be assessed and that CMS may require a corrective action plan. The notice would provide a deadline for the provider or facility to respond; HHS anticipates a typical deadline of 14 days. In response to a noncompliance notice, providers or facilities could submit any relevant documentation, including medical bills, notice and consent forms signed by the patient or patient representative, or proof of public disclosure of patient protections against balance billing. Providers or facilities also could submit any evidence documenting internal policies and procedures related to compliance. HHS proposes to limit enforcement action to six years from the date of alleged violations.

Providers or facilities that receive a noncompliance notice could request an extension; possible rationales for extensions could include limited staffing resources or requests for clarification on the alleged violation.

Provider/Facility Penalties. The No Surprises Act establishes a civil monetary penalty of up to $10,000/violation for providers/facilities. In the proposed rule, HHS suggests that CMS would consider the nature of the violation, the culpability of the provider or facility, the provider or facility's past history of violations, the frequency of violations (i.e., whether the issue represents a pattern or is an isolated incident), and the level of financial or other impacts on affected individuals in determining penalty amounts. In instances where there are significant mitigating circumstances (e.g. no previous complaints against the provider or facility, demonstration that the issue is an isolated occurrence), the CMP would be assessed to be sufficiently below the $10,000 maximum. On the other hand, in instances where CMS determines there are aggravating circumstances (e.g. the violation indicates a widespread pattern of abuse, the provider or facility does not provide documentation showing that the violations were corrected) the CMPs would be close or equal to the $10,000 maximum. Finally, CMS may waive the CMP entirely if the provider or facility unknowingly violated the requirement, as long as any erroneous bills are withdrawn and patients are reimbursed

within 30 days of the violation. HHS also proposes to codify the hardship exemption described in the No Surprises Act.

HHS proposes that, should CMS decide to impose CMPs, the agency would need to serve notice of the action in accordance with current practices, and the notice would need to specify the amount of the CMP, the information considered to determine the amount, and the process for appealing. HHS also proposes an appeals process in the proposed rules. If a provider or facility does not initiate the process within 30 days of the notice or show good cause for failing to initiate the process, the CMP determination would be final.

Plan Penalties. The No Surprises Act established that plan and issuer CMPs will be based on current regulation instituting penalties for PHS Act violations. Based on those regulations, the maximum penalty on plans/issuers is $100/day per violation, adjusted annually.

Effective Date: January 1, 2022

Helpful Links:

- **Statute:** See the following sections of the "No Surprises Act" as part of the Consolidated Appropriations Act, 2021 ○ Sec. 102. Health insurance requirements regarding surprise medical billing. ○ Sec. 104. Health care provider requirements regarding surprise medical billing.
- **Regulations:**
  - See the following sections of the Code of Federal Regulations, as discussed in the Interim Final Rule: Requirements Related to Surprise Billing; Part I
    - **ERISA:** 29 CFR Part 2590.716-7
    - **Individual and Fully Insured Markets:** 45 CFR 149.150
    - **Federal Employee Health Benefit Plans:** 5 CFR 890.114 ○ Proposed Rule Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement (45 CFR parts 150)
  - **Other Federal Guidance:**
  - N/A

Frequently Asked Questions

1) **Will health plans be subject to the same oversight and enforcement as providers?** Yes. While the legislation and regulations appear to contain more emphasis on provider oversight and enforcement, this is because the law and regulations had to establish new processes for providers whereas they could largely rely on existing health plan oversight and enforcement provisions.

2) **How do I know if the state or the federal government is conducting oversight?** Generally, states are responsible for oversight and enforcement of all provisions in the No Surprises Act. However, they may defer their oversight to the federal government or the federal government may step in if it does not believe the state is fulfilling its responsibilities. We encourage you to work closely with your state hospital association to determine the oversight and enforcement process in your states.

3) **When does state law apply, and when does federal law apply?** We share your concern about the lack of clarity. We have created this chart to help identify when one or both sets of laws may apply.

4) **What if state law addresses balance billing but does not have a reimbursement method?** In this instance, the state law would apply for purposes of the ban on balance billing, but the federal approach to reimbursement would apply.

5) **What happens when the federal law is more advantageous to the consumer or more expansive than the state law?** In general, the federal law applies if it is more protective of the consumer.

OVERSIGHT/ENFORCEMENT CHARTS

Interaction with State Law: Balance Billing

State Primary on Oversight/Enforcement

Scenario: Patient care occurs in the same state that regulates the provider/facility.	Federal Law Applies	State Law Applies	Both State & Federal Law Applies
State-regulated plan, no state law	Yes	N/A	N/A
State-regulated plan, state law covers full scope of services and includes policy for provider reimbursement	No	Yes	No
State-regulated plan, state law covers some of the services or otherwise is not as comprehensive as federal law	Partial	Partial	Yes
Federally-regulated plan, no state law and/or has not opted into state law	Yes	No	No
Federally-regulated plan, opted in to state law that covers full scope of services and includes policy for provider reimbursement	No	Yes	No
Federally-regulated plan, opted in to state law that covers some of the services or otherwise is not as comprehensive as federal law	Partial	Partial	Yes

Interaction with State Law: Balance Billing (Other Scenarios)

Other Scenarios:	Federal Law Applies	State Law Applies	Both State & Federal Law Applies
Patient lives in a state with balance billing protections but the out-of-network care is provided in another state without balance billing protections.	Yes, regardless of type of health coverage	No	No
Patient in a state-regulated health plan (or federally regulated health plan that has opted into state law) receives out-of-network emergency and post-stabilization services in a state with a balance billing law that only offers patient protections and a provider reimbursement approach for the emergency services only	Yes for the post-stabilization services only when the patient has state-regulated coverage or the plan has opted into the state	Yes for the emergency services only when the patient has state-regulated coverage or the plan has opted into the state	Yes – federal law "wraps around" the state protections
Patient in a state-regulated health plan (or federally regulated health plan that has opted into state law) that is more expansive than federal law	No	Yes	No
Patient is in any form of coverage in a state that has applied balance billing protections through its regulation of providers, not health plans	Maybe	Yes	Maybe