

Implementing the No Surprises Act in Family Planning Settings

Though the practice of "surprise billing" is not common in the family planning safety net, the No Surprises Act applies to publicly funded family planning providers, because these settings serve commercially insured, uninsured, and self-pay patients. The purpose of this guide is to assist family planning providers and administrators with developing systems and policies to ensure compliance with the No Surprises Act (NSA) at the health centers they oversee and fund.

On January 1, 2022, NSA went into effect to protect consumers against "surprise billing." In the context of family planning and sexual health care delivery, surprise billing typically impacts two categories of patients:

Commercially insured patients who unknowingly receive care from an out-of-network provider or facility, including instances where a patient's provider recently stopped contracting with their health insurance plan. They later receive a bill exceeding their innetwork amount for scheduled, non-emergency services.

Uninsured or self-pay patients, including patients with adjusted fees based on their income, who receive a bill from a health care provider or facility for scheduled, non-emergency services that exceeds the amount expected or disclosed when the patient consented to care.

The NSA regulations set a method for determining patient cost sharing in the above situations, as well as for situations involving provision of emergency services, specifically in the 22 states that have not enacted comprehensive laws to protect consumers from **balance billing.** It also requires that all uninsured and self-pay patients receive a **Good Faith Estimate** in advance of receiving scheduled, non-emergency services.

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KEY TERMS

BALANCE BILLING

The amount billed to the patient after discounts, insurance payments and adjustments have been applied.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

Federal government agency that oversees both the Medicare and Medicaid programs.

GOOD FAITH ESTIMATE

A notification that outlines an uninsured or self-pay individual's expected charges for a scheduled or requested service(s) or item(s).

OUT-OF-NETWORK

Refers to physicians, hospitals, and other health care providers who are not contracted with a particular commercial health insurance plan.

SURPRISE BILLING

A surprise medical bill is an unexpected bill from an out-of-network provider or out-of-network facility, or for an amount greater than expected or outlined in the Good Faith Estimate provided.

PATIENT-PROVIDER DISPUTE RESOLUTION PROCESS (PPDR)

A charge resolution process for an uninsured (or self-pay) patient, or their authorized representative. This process brings in an independent third party called a dispute resolution entity to determine the appropriate amount the patient must pay.

SELECTED DISPUTE RESOLUTION ENTITY

Organizations that are certified by the US Department of Health and Human Services (HHS), the Department of Labor, and the Department of Treasury to serve as independent dispute resolution entities in PPDR process for the NSA.

INDEPENDENT DISPUTE RESOLUTION

The procedure by which the Selected Dispute Resolution entity reviews and resolves the charge dispute submitted via the PPDR process.

Overview

Regulations

Regulations pertaining to the NSA law have been issued by four different federal government agencies: HHS; the Departments of Labor and Treasury; and the Office of Personnel Management, which is the federal government's civilian workforce human resources arm. Additional guidance and documentation also have been published by CMS, as well as in the Federal Register.

Applicability

NSA requirements apply to individuals enrolled in commercial health insurance plans, including:

- Employment-based group health plans (both self-insured and fully insured);
- Individual or group health coverage on or outside federally facilitated or state-based marketplaces;
- Federal Employee Health Benefit (FEHB) health plans;
- Non-federal governmental plans sponsored by state and local government employers;
- Certain church plans within Internal Revenue Service (IRS) jurisdiction; and
- Student health insurance coverage, as defined by 45 CFR 147.145.²

NSA requirements do not apply to all patients with health insurance coverage. CMS has explicitly excluded patients with coverage through Medicare, Medicaid, Indian Health Services, Veterans Affairs Health Care, and TRICARE from NSA requirements, as these programs already have regulations in place to protect against unexpected medical bills.³

All remaining patient populations – insured and uninsured – and licensed health care facilities that serve them are encompassed by the NSA ruling.⁴ This includes patients served by licensed health care facilities that serve high proportions of patients with public health insurance coverage, for example:

- Title X-funded health care providers;
- Federally qualified health centers;
- Public Health Service Act-funded health ceners;
- Hospitals and hospital outpatient departments;
- Rural health centers;
- · Laboratory centers; and
- Imaging centers.

What About Medicaid and Medicare Beneficiaries?

The NSA does not apply to individuals with health insurance coverage through Medicaid and Medicare, as they are already covered from surprise billing through the existing rights and protections established for these programs. Both traditional fee-for-service and managed care plans for the Medicaid and Medicare programs afford their beneficiaries with rights and protections, including the right to receive clear and simple information regarding what services are covered, what the patient's health insurance plan will cover, and the patient's financial responsibility.

¹ No Surprises Act, included in the Consolidated Appropriations Act, 2021. Amended title XXVII of the Public Health Service Act. Public Law 116-260 (2021).

⁴⁵ CFR 147.145 defines student health insurance coverage as a type of individual health insurance coverage that is provided by an institution of higher education, through a written agreement with a health insurance issuer. Health insurance coverage is provided to students enrolled in that institution of higher education and their dependents.

³ Centers for Medicare and Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight (CCIIO), *Guidance on Good Faith Estimates and the Patient-Provider Dispute Resolution (PPDR) Process for Providers and Facilities as Established in Surprise Billing* (Washington, DC, 2021), 8, https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-Good-Faith-Estimate-Patient-Provider-Dispute-Resolution-Process-for-Providers-Facilities-CMS-9908-IFC.pdf.

^{4 &}quot;Requirements for provision of good faith estimates of expected charges for uninsured (and self-pay) individuals," *Code of Federal Regulations*, title 45 (2021): § 149.610 (a)(2)(vii-viii).

Implementing the No Surprises Act in Family Planning Settings

Discussed in greater detail in subsequent sections of this document, the NSA requirements related to disclosure of balance billing protections, provision of Good Faith Estimates, and the PPDR process also apply to providers working in licensed health care settings that treat uninsured and self-pay patients, including patients who do not wish to

use their health insurance coverage due to confidentiality concerns. More specifically, these health care providers include clinicians and other health care providers who are reimbursed for acting within the scope of practice of their license or certification under applicable state law, including behavioral health providers.

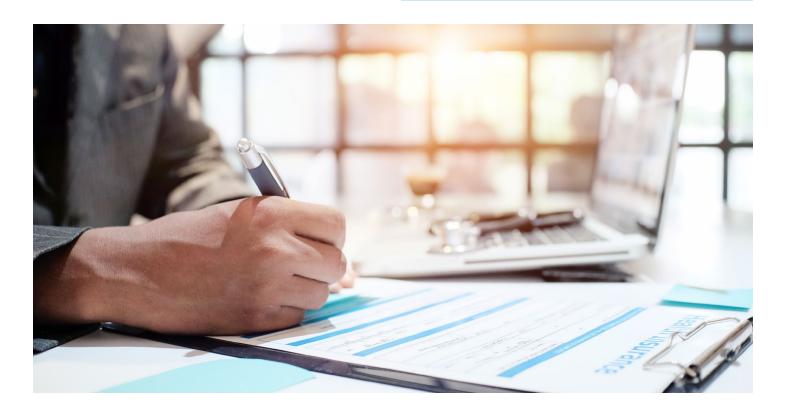
State-Level Balance Billing Protections

Prior to the inception of the NSA, many Americans were vulnerable to surprise or balance billing for out-of-network services. Of note, prior to the NSA, 17 states had not enacted balance billing protection laws and 15 states only had enacted limited-protection balance billing laws.⁵

The federal NSA requirements are generally more expansive than existing state-level balance billing protection laws. Publicly funded family planning providers, including Title X-funded providers, should ensure their practices conform to the broader federal rules.

Of note, many state laws in place prior to the NSA principally related to services provided in emergency departments and for non-emergency services provided by out-of-network facilities. They do not address balance billing of uninsured or self-pay patients, which make up 36% of patients service in Title X settings. Furthermore, none of the state laws required health care providers to furnish uninsured and self-pay patients with a Good Faith Estimate for scheduled services.

See *Appendix A – State-Level Balance Billing Protections* for a map of states with comprehensive or limited state-level balance billing protections.



⁵ Maanasa Kona, "State Balance-Billing Protections," Commonwealth Fund (map), last updated Feb. 5, 2021, https://doi.org/10.26099/0x7j-7731.

⁶ C.I. Fowler, J. Gable, and B. Lasater, "Family Planning Annual Report: 2021 National Summary," (Washington, DC: Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services, 2022), ES-2.

No Surprises Act Requirements

Disclosure of Balance Billing Protections

The NSA requires that any patient that is a participant, beneficiary, or enrollee in a commercial health insurance plan receives the following from their health care provider: (1) a disclosure of balance billing protections and (2) information on how to report violations. It also requires that health care providers and facilities post this information prominently at the location of the facility, post it on a public website (if applicable), and provide it to the participant, beneficiary, or enrollee in a timeframe and manner outlined in the NSA regulation.

In addition, NSA regulations require that patients who are uninsured or self-pay, including those that do not wish to have a claim filed to their health insurance plan, receive disclosure of balance billing protections and information on reporting violations.

For an example of a plain language disclosure document that can be provided to patients, see *Appendix B – Standard Notice and Consent Documents Under the No Surprises Act.* This document was developed by HHS to support NSA implementation. It may be used or adapted by health centers to provide cost estimates and disclosure of balance billing protections to applicable patients.

The Good Faith Estimate

All uninsured and self-pay patients should receive a "Good Faith Estimate" for the expected charges in advance of scheduled services, as well as upon request. Specifically, all uninsured and self-pay individuals should receive a single, comprehensive Good Faith Estimate notifying them in "clear and understandable language" of their expected service(s) and itemized charges for those expected services.

Good Faith Estimates should include the following information. See *Appendix C – Sample Good Faith Estimate Form and Instructions* for an example of this document.

Visit Information

- The patient's name and date of birth.
- The date or defined period of care on which the primary service(s) or item(s) are scheduled, if applicable.
- The primary service(s) or item(s) that will be furnished to the patient by the primary provider, as based on the reason for the scheduled visit.
 - This includes a description of the primary service or item in clear and understandable language.
- The names, National Provider Identifiers, and Tax Identification Numbers of each provider or facility that will be furnishing service(s) or items as part of the

scheduled visit; and the state(s) and facility location(s) where the services or items are expected to be provided.

Scheduled Services and Items

- A list of all services and items, grouped by each provider or facility, that are reasonably expected to be provided as part of or in conjunction with the scheduled primary service(s) or item(s).
 - This list must include any service(s) or item(s) that may be provided by other providers and/or facilities as part of the scheduled services during the period of care (e.g., contracted arrangements or referrals for tests or services).
 - Listed services and items may include any of the following:
 - » Encounters;
 - » Procedures;
 - » Medical tests;
 - » Supplies;
 - » Prescriptions drugs;
 - » Durable medical equipment; and
 - » Fees (including facility fees).

⁷ The Plain Language Action and Information Network (PLAIN) has issued official guidance on the Plain Language Act of 2010, including a comprehensive guidelines document.

BEST PRACTICE: If a patient schedules an appointment for contraception, but does not know what method they desire at the time of scheduling, the health center should append to the Good Faith Estimate a cost schedule with the different costs associated with all available contraceptive options. This document should include the cost of supplies, as well as long acting reversible contraception (LARC) insertion procedures.

- The Good Faith Estimate also must include applicable ICD-10 diagnosis codes, expected CPT/HCPCS service codes, and expected charges associated with each listed service or item.
- A list of any services or items that the primary provider anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary service(s) or item(s).

Notices

- The Good Faith Estimate must include a disclaimer directly above the list of services and items that includes the following information:
 - That Good Faith Estimates are issued to all uninsured or self-pay individuals upon scheduling or request.
 - Instructions for how an uninsured or self-pay individual can obtain Good Faith Estimates for services or items.
- The Good Faith Estimate also must include the following:
 - Disclaimer informing the uninsured or self-pay individual that there may be additional services or items the primary provider recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the Good Faith Estimate.
 - Disclaimer informing the uninsured or self-pay individual that the information provided in the Good Faith Estimate is only an estimate regarding services or items reasonably expected to be furnished to the patient; actual services, items, or charges may differ from the Good Faith Estimate.

- Disclaimer informing the uninsured or self-pay individual of their right to initiate the PPDR process if the actual billed charges are substantially in excess of the expected charges included in the Good Faith Estimate.
 - » This disclaimer must include instructions for where the patient can find information about how to initiate the PPDR process.
 - » The disclaimer also must state that the initiation of the PPDR process will not adversely affect the quality of health care services furnished to the patient by a provider.
- Disclaimer that the Good Faith Estimate is not a contract and does not require the uninsured or selfpay individual to obtain the services or items from any of the providers identified in the Good Faith Estimate.

As a best practice, the provider should confirm patient understanding of cost estimates and disclaimers in the Good Faith Esitmate by having them sign the form.

From January 1, 2022, through December 31, 2022, HHS will exercise its enforcement discretion in situations where a Good Faith Estimate provided to an uninsured or self-pay individual does not include expected charges from other providers and facilities that are involved in the patient's care.

Implementing Requirements

Determining Expected Charges

The expected charges listed on a Good Faith Estimate should be the approved cash pay rate or the amounts that an uninsured or self-pay individual, based on financial information provided, would be expected to pay for services or items listed on the Good Faith Estimate after any anticipated discounts or adjustments. Specifically, the Good Faith Estimate's expected charges should account for any discounts that would be applied under the provider's Financial Assistance Policy, including Title X and/or Section 330 health center sliding fee discount programs.

In determining expected charges, providers and facilities are expected to use the ICD-10 diagnosis and CPT/HCPCS procedure coding that best describes each service and item listed in the Good Faith Estimate. Providers and facilities are expected to follow National Correct Coding Initiative (NCCI)/Unbundling edit guidelines by choosing the most comprehensive service code(s) available. When a single service code is available that captures reporting and billing for all components of a service or item, the Good Faith Estimate should use that single service code and expected charge to capture the most comprehensive coding level.

The primary provider or facility must include any service or item that is reasonably expected to be provided in conjunction with the primary service, including services provided by another provider or facility ("co-provider" or "cofacility"). As a result, the Good Faith Estimate may contain expected charges for multiple entities: the primary provider, plus co-providers or co-facilities that furnish items and services that are customarily provided in conjunction with a primary service or item. For example, if a patient schedules a visit for sexual transmitted infection (STI) screening, the primary provider's Good Faith Estimate would include the cost of the visit, plus the costs of any labs or tests. If the provider does not offer point-of-care testing and also does not contract with an outside lab, a commercial lab would be listed as a co-provider on the Good Faith Estimate, along with cost estimates for any services that the lab is expected to bill the patient directly.

For more examples of how family planning and sexual health services providers may calculate Good Faith Estimates for common scenarios, see *Appendix D – Good Faith Estimate Scenarios and Examples*.

Changes to Scope of Care

If the primary provider, facility, co-provider, or co-facility anticipates or is notified of any changes to the scope of a Good Faith Estimate (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities) previously furnished at the time of scheduling, the primary provider must provide the individual with a new Good Faith Estimate no later than one business day before the scheduled visit.

If any changes in expected providers or facilities represented in a Good Faith Estimate occur less than one business day before the scheduled visit, the replacement provider must accept the Good Faith Estimate for the relevant service(s) and/or item(s) being furnished that was provided by the initial provider.



⁸ The Cash Pay Rate is the amount the provider will accept as payment for a service (or item) if the amount is paid in full prior to or at the time of the furnishing of the service.

Good Faith Estimate Timeframes

A provider must provide information about the availability of a Good Faith Estimate to uninsured or self-pay patients when scheduling a visit or when a patient inquires about the cost of services. Any inquiry regarding cost by an uninsured or self-pay individual should be considered a request for a Good Faith Estimate and, therefore, should meet all Good Faith Estimate content requirements.

The primary provider must provide a Good Faith Estimate to uninsured or self-pay patients within the following timeframes:

- When a service is scheduled at least three business days before the visit, the Good Faith Estimate must be provided within one business day after the date of scheduling.
- When a service is schedule at least 10 days before the visit, the Good Faith Estimate must be provided within three business days after the date of scheduling.

Upon receiving a request for a Good Faith Estimate or upon scheduling a primary service or item for an uninsured or self-pay individual, the primary provider must contact all coproviders and co-facilities who are reasonably expected to provide services or items in conjunction with, and in support of, the visit no later than one business day after scheduling or receiving the request. The primary provider must request that the co-providers submit Good Faith Estimate information to the primary provider.



CMS guidance, issued in a April 2022 CMS NSA Frequently Asked Questions (FAQ) document, regarding the timeframe rules indicates that providers and facilities are not required to provide a Good Faith Estimate for services that are not scheduled at least three business days in advance, (e.g., if a patient receives emergent or other services on an unscheduled or walk-in basis).9

Regardless of whether the three business day advance appointment requirement applies, providers and facilities still should ensure that all uninsured or self-pay patients understand their right to receive a Good Faith Estimate. They can do this by:

- Inquiring whether a patient is uninsured or self-pay; and
- Providing oral and written communication regarding the availability of and right to receive of a Good Faith Estimate when a service is scheduled at least three business days in advance.

An individual also may request and obtain a Good Faith Estimate for services and items when requested, even if they ultimately do not schedule a visit. This allows for consumers to compare costs and/or consider if they will submit a claim to their health insurance carrier or pay out-of-pocket (self-pay) for services.

HHS has enforcement discretion and recognizes that some providers or facilities may need to establish efficient and secure communication channels for transmission of Good Faith Estimate information between primary providers and co-providers. HHS also understands that it may take time for providers to develop systems and processes for receiving and providing required information from co-providers and co-facilities. Therefore, for Good Faith Estimates provided to uninsured or self-pay individuals from January 1, 2022, through December 31, 2022, HHS will exercise its enforcement discretion in situations where estimates provided do not include all expected service details from co-providers.¹⁰

⁹ CMS, CCIIO, Frequently Asked Questions for Providers About the No Surprises Rules (Woodlawn, MD, April 6, 2022), https://www.cms.gov/files/document/faq-providers-no-surprises-rules-april-2022.pdf.

¹⁰ CMS, CCIOO, "The No Surprises Act's Good Faith Estimates and Patient-Provider Dispute Resolution Requirements." Webinar (Slide 28), Woodlawn, MD, February 25, 2022.

Methods for Providing Good Faith Estimates

The Good Faith Estimate is provided in written form either on paper or electronically based on the uninsured or self-pay patient's preferred method. Timeframes must be followed as above and, if delivered via mail, the Good Faith Estimate must be postmarked in the required timeframe.

As a best practice, patients confirm their understanding of cost estimates and disclaimers by signing the Good Faith Esitmate form. If the health center provides the patient with a paper form by mail, it may wish to provide the patient with a paper copy of the form to sign at visit check in. Forms

provided electronically may have the option for patients to sign their name electronically.

Due to the sensitive nature of family planning and sexual health services, providers and facilities should have policies in place to confirm and ensure that the patient's preferred method of receiving the Good Faith Estimate is carefully followed. Not having these important safeguards in place may compromise the confidentiality guaranteed to all patients seeking Title X-funded care and other sensitive services and the patient's safety.

Additional Good Faith Estimate Requirements

Retention

A Good Faith Estimate issued to an uninsured or selfpay individual is considered part of the patient's medical record. It must be maintained and retained using the same standards as a medical record.

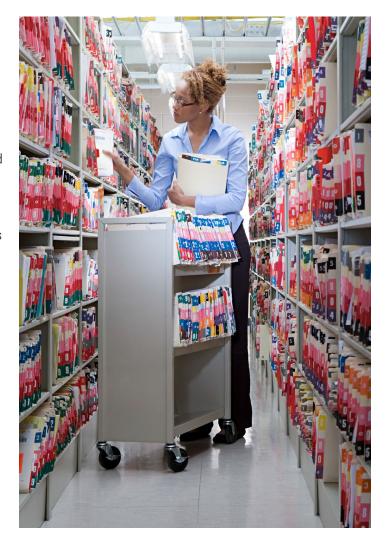
Furthermore, upon request, primary providers and facilities must provide copies of any previously issued Good Faith Estimates furnished within the last six years to an uninsured or self-pay patient.

Federal vs. State Requirements

For all providers or facilities that issue Good Faith Estimates following their state's processes and rules, if those state processes and rules do not meet federal Good Faith Estimate requirements, those providers and facilities have failed to comply with federal Good Faith Estimate requirements.

Acting in Good Faith

A provider will not fail to comply with federal Good Faith Estimate requirements solely because, despite acting in good faith and with reasonable due diligence, they make an error or omission in a Good Faith Estimate, provided that the error is corrected as soon as practicable. Nevertheless, if services or items are delivered before an error in a Good Faith Estimate is addressed, the provider may be subject to PPDR if the actual billed charges are substantially higher than the estimate provided.



Patient-Provider Dispute Resolution

The PPDR Process

Beginning January 1, 2022, a PPDR process will be available for uninsured or self-pay individuals who receive a bill from a provider that is "substantially in excess" of the charges provided in the Good Faith Estimate. Under the PPDR process, these patients may seek a determination from a Selected Dispute Resolution entity of the amount they ultimately must pay for services and items received.

The PPDR process can apply to any service or item furnished by a primary provider, primary facility, co-provider, or co-facility to an uninsured or self-pay individual where the total billed charges are substantially in excess of the total expected charges in the Good Faith Estimate.

HHS regulations establish that, when the billed charges for any provider are in excess of the Good Faith Estimate by \$400 or more, the service or item may be eligible for payment determination by a Selected Dispute Resolution entity through the PPDR process.¹¹

As each Good Faith Estimate could potentially contain expected charges from multiple providers and facilities, the substantially in excess determination is made separately for each unique provider or facility listed on the Good Faith Estimate. Specifically, to determine eligibility for PPDR:

- For each provider or facility, the total expected charges for each service or item provided should be combined.
- This total amount then is compared with the total of all billed charges for the specific provider or facility, including billed charges for services and items that were furnished but not included in the Good Faith Estimate.

An uninsured or self-pay individual, or their authorized representative, can initiate the PPDR process by submitting an initiation notice to HHS through the online federal Independent Dispute Resolution portal, submitting an

initiation notice electronically, or submitting an initiation notice by mail if postmarked within 120 calendar days of receiving the initial bill containing excess charges. HHS strongly recommends that patients utilize the federal Independent Dispute Resolution portal to ensure the request can be processed quickly and securely. 12

Once the PPDR process is initiated, the Selected Dispute Resolution entity will notify the provider that they must provide certain information within 10 business days. HHS strongly recommends the provider use the online federal Independent Dispute Resolution portal to submit this documentation, which includes the following:

- A copy of the Good Faith Estimate provided to the patients for the services or items under dispute;
- A copy of the billed charges for the services or items under dispute; and
- If available, documentation to demonstrate that the difference between the billed charges and the expected charges in the Good Faith Estimate reflects the costs of a medically necessary service or item and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider when furnishing the Good Faith Estimate.

The Selected Dispute Resolution entity will make a determination regarding the amount to be paid by the patient no later than 30 business days after receiving this information form the provider.

See Appendix E - Guidance for Selected Dispute Resolution Entities: Required Steps to Making a Payment Determination under the PPDR Process for guidance from HHS on the PPDR process and payment resolution.

Practice Requirements During the PPDR Process

While the PPDR process is pending, the provider must not move the bill for the disputed service(s) or item(s) into collection or threaten to do so. If the bill has already moved

to collection, the providershould cease collection efforts and suspend the accrual of any late fees until after the PPDR process has concluded.

¹¹ CMS, CCIOO, "The No Surprises Act's Good Faith Estimates and Patient-Provider Dispute Resolution Requirements." Webinar (Slide 62), Woodlawn, MD, February 25, 2022.

¹² Ibid., Slide 61.

References

C.I. Fowler, J. Gable, and B. Lasater, "Family Planning Annual Report: 2021 National Summary," (Washington, DC: Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services, 2022), ES-2.

Centers for Medicare and Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight (CCIIO), Frequently Asked Questions for Providers About the No Surprises Rules (Woodlawn, MD, April 6, 2022), https://www.cms.gov/files/document/faq-providers-no-surprises-rules-april-2022.pdf.

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CMS, CCIOO, "The No Surprises Act's Good Faith Estimates and Patient-Provider Dispute Resolution Requirements." Webinar, Woodlawn, MD, February 25, 2022.

Jack Hoadley, Kevin Lucia, and Maanasa Kona, "State Efforts to Protect Consumers from Balance Billing," *To the Point* (blog), Commonwealth Fund, Jan. 18, 2019. https://doi.org/10.26099/g10e-a246.

US Department of Health and Human Services, *Standard Notice and Consent Documents Under the No Surprises Act* (Washington, DC, July 2021). www.cms.gov/files/document/standard-notice-consent-forms-nonparticipating-providers-emergency-facilities-regarding-consumer.pdf.

US General Services Administration (GSA), plainlanguage.gov, *Federal Plain Language Guidelines* (Washington, DC, May 2011), https://www.plainlanguage.gov/media/FederalPLGuidelines.pdf.

This document was prepared by the National Family Planning & Reproductive Health Association (NFPRHA), in consultation with RT Welter and Associates. It is intended for informational purposes and does not constitute legal or medical advice or NFPRHA's endorsement of a specific product.

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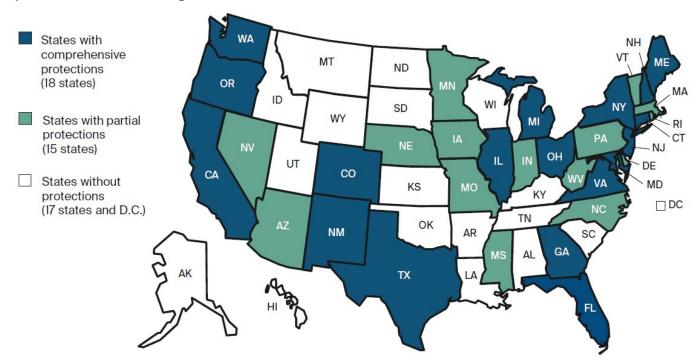
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Appendices

Appendix A: State-Level Balance Billing Protections

The map below was produced by the Commonwealth Fund in 2021 [prior to the enactment of the No Surprises Act (NSA)] to illustrate those states with comprehensive or partial state-level protections from balance billing.

Map 1. State Balance-Billing Protections



Source: Maanasa Kona, "State Balance-Billing Protections," Commonwealth Fund (map), last updated Feb. 5, 2021, https://doi.org/10.26099/0x7j-7731.

The Commonwealth Fund used the following criteria when identifying states with **comprehensive billing protections:**

- Extend protections to both emergency department and in-network hospital settings.
- Apply laws to all types of insurance, including all managed care plans.
- Protect consumers by holding them harmless from extra provider charges, meaning providers are prohibited from balance billing and patients are not responsible for charges.
- Adopt an adequate payment standard, meaning there are rules to determine how much the insurer pays the provider, or, at the very least, there is a dispute-resolution process to resolve payment disputes between providers and insurers.

Criteria for state laws that offer "limited" protections are as follows:

- Extend protections to emergency department <u>and/or</u> innetwork hospital settings.
- Apply to Health Management Organizations (HMOs) and/ or Preferred Provider Organizations (PPOs).
- Include some language that protects consumers from extra provider charges.

Some states with one or more of the limited protections above also may have specific payment standards either through a standard or dispute resolution process.

Of note, none of the above (i.e., comprehensive, limited) state-level protections apply to uninsured or self-pay consumers. Furthermore, the state laws in place prior to

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the NSA are narrow in scope, principally relating to services provided in emergency departments and for non-emergency services provided by out-of-network facilities. Because of the limitations of all these state-level balance billing laws, all publicly funded family planning and sexual health services providers, including Title X-funded providers, should default to the new federal requirements of the NSA.

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Appendix B: Standard Notice and Consent Documents Under the No Surprises Act

Good Faith Estimate for Health Care Items and Services

Patient				
Patient First Name	Middle Name		Last Name	
Patient Date of Birth:				
Patient Identification Number:				
Patient Mailing Address,	Phone Number	, and E	Email Address	
Street or PO Box			Apartment	
City			State	ZIP Code
Phone		Email A	Address	
Patient's Contact Preference:	[] By mail [] E	By email		
Patient Diagnosis				
Primary Service or Item Requeste	ed/Scheduled			
Patient Primary Diagnosis			Primary Diagnosis Co	de
Patient Secondary Diagnosis			Secondary Diagnosis	Code
If scheduled, list the date(s) the Pi	rimary Service or Ite	em will be	e provided:	
Check this box if this service	or item is not yet sc	heduled		
Date of Good Faith Estimate:				

Summary of Expected Charges					
(See the itemized estimate attached for more detail.)					
Provider Name	Estimated Total Cost				
Provider Name	Estimated Total Cost				
Provider Name	Estimated Total Cost				
	Total Estimated Cost: \$				

The following is a detailed list of expected charges for scheduled for

Provider/Facility Na	ovider/Facility 1] Estimate ovider/Facility Name			Provider/Facility Type			
Ovident denty Name			Froviden/Facility Type				
Street Address							
City	State				Zip code		
Contact Person		Phone		Email			
National Provider Id	dentifier		Taxpayer	Identificatio	l n Number		
-4-!!£0!	and the war for ID was idea	/F !!!4	41				
etalis of Servi	ces and Items for [Provide		1]	1			
	Address where service/item v	vill	nosis Code	Service C	Code	Quantity	Expected Cost
	Address where service/item v	vill		Service (Code	Quantity	Expected Cost
	Address where service/item v	vill		Service (Code	Quantity	Expected Cost
	Address where service/item v	vill		Service (Code	Quantity	Expected Cost
	Address where service/item v	vill		Service (Code	Quantity	Expected Cost
	Address where service/item v	vill		Service (Code	Quantity	Expected Cost
Service/Item	Address where service/item v	vill Diag	gnosis Code	Service (Code	Quantity	Expected Cos
Service/Item Total Expected	Address where service/item value provided	vill Diag	gnosis Code	Service (Code	Quantity	Expected Cost

riovider/racility N	er/Facility Name			Provider/Facility Type				
Street Address								
City	State				Zip code			
Contact Person		Phone		Email		Phone Email		
National Provider I	dentifier		Taxpayer	Identification	ion Number			
	ione and Itama for IDravida	-						
	Address where service/item	will		Service C	ode	Quantity	Expected Cos	
		will	y 2] agnosis Code	Service C	code	Quantity	Expected Cos	
	Address where service/item	will		Service C	code	Quantity	Expected Cos	
Service/Item	Address where service/item	will		Service C	code	Quantity	Expected Cos	
Service/Item	Address where service/item	will Dia	agnosis Code	Service C	code	Quantity	Expected Cos	

rovider/Facility Na	vider/Facility Name			Provider/Facility Type				
Street Address								
City	State				Zip code			
Contact Person		Phone Email						
National Provider I	dentifier		Taxpayer	Identification	n Number			
etails of Serv	ices and Items for [Provider/Fa	acility 3]						
Service/Item	Address where service/item will be provided	Diagno	osis Code	Service C	ode	Quantity	Expected Cost	
Service/Item		Diagno	osis Code	Service C	ode	Quantity	Expected Cost	
Service/Item		Diagno	osis Code	Service C	ode	Quantity	Expected Cost	
Service/Item		Diagno	osis Code	Service C	ode	Quantity	Expected Cost	
Service/Item		Diagno	osis Code	Service C	ode	Quantity	Expected Cost	
Service/Item		Diagno	osis Code	Service C	ode	Quantity	Expected Cos	
				Service C	ode	Quantity	Expected Cost	
	be provided			Service C	ode	Quantity	Expected Cos	

Disclaimer

This Good Faith Estimate shows the costs of items and services that are reasonably expected for your health care needs for an item or service. The estimate is based on information known at the time the estimate was created.

The Good Faith Estimate does not include any unknown or unexpected costs that may arise during treatment. You could be charged more if complications or special circumstances occur. If this happens, federal law allows you to dispute (appeal) the bill.

If you are billed for more than this Good Faith Estimate, you have the right to dispute the bill.

You may contact the health care provider or facility listed to let them know the billed charges are higher than the Good Faith Estimate. You can ask them to update the bill to match the Good Faith Estimate, ask to negotiate the bill, or ask if there is financial assistance available.

You may also start a dispute resolution process with the U.S. Department of Health and Human Services (HHS). If you choose to use the dispute resolution process, you must start the dispute process within 120 calendar days (about 4 months) of the date on the original bill.

There is a \$25 fee to use the dispute process. If the agency reviewing your dispute agrees with you, you will have to pay the price on this Good Faith Estimate. If the agency disagrees with you and agrees with the health care provider or facility, you will have to pay the higher amount.

To learn more and get a form to start the process, go to www.cms.gov/nosurprises/consumers or call 1-800-985-3059.

For questions or more information about your right to a Good Faith Estimate or the dispute process, visit www.cms.gov/nosurprises/consumers or call 1-800-985-3059.

Keep a copy of this Good Faith Estimate in a safe place or take pictures of it.

You may need it if you are billed a higher amount.

Implementing the No Surprises Act in Family Planning Settings

Appendix C: Sample Good Faith Estimate Form and Instructions

Provider/Facility Name:						
National Provider Identification	er(s):	Tax Identifica	tion Number:			
Good Faith Estimate for Services This document is a cost estimate for how much you can expect to pay for your scheduled appointment at You may also be receiving this document because you requested cost information before scheduling an appointment. Patient Information Last Name, First Name and Middle Initial Date of Birth: Patient ID#: Insurance Status: □ Self-pay □ Other:						
income and family size, determine which Sliding estimate may change with Group, or if your house. SFS Payment Group: See Appendix A for information determines SFS payments.	ormation on how The any any dis	ooking to receing group you be confirm	ve. Our staff long to. The t s your SFS P es below do r ou may be eli	will help you below cost Payment not include igible for a		
Service Scheduled or Service Description:	Requested					
Scheduled Date of Service	ce:	_ □ Service	has not been	scheduled		
	Service Description (Code)	Diagnosis Code*	Retail Cost	Discounted Cost		
Total Estimated Costs	** from					
	may not know the diagnosis code one year from the Good Faith Es		et.			
☐ Additional providers or f additional cost estimates ar	acilities are expected to provid	de services or it	-			

Take a picture and/or keep a copy of this document. It contains important information about your rights and protections.

	For Interna	l Use		
	onfidential services?		□ No	
	iver Good Faith Estimate by	/ :	□ Db/b-	4
	☐ Email/patient portal		☐ Phone/te ☐ Do not c	
U Other mailing address				Ontact
Cood Foith F	Estimates for Addition	anal Dravid	oro or Ec	a dilitia a
Good Faith E	Sumates for Addition	Jilai Pioviu	eis oi ra	aciiille5
If the below section is co	empleted, there may be add	ditional costs fo	r your visit f	from another
provider or facility.			·	
Co-Provider/Co-Facility	1 Name:			
Address:				
National Provider Identifier	(s):			
	Service Description			Discounted
	(Code)	Code*	Cost	Cost
Total Estimated Costs	s** from			
Co-Provider/Co-Facility 2	2 Name:			
Address:				
City:				
National Provider Identifier	. ,	Tax Identific		
	Service Description	Diagnosis Code*		Discounted
	(Code)	Code	Cost	Cost
Total Estimated Costs	s** from			
	not know the diagnosis code(s) f			
**Estimated costs are valid for	r one year from the Good Faith E	stimate date.		
Notes about additional				
anticipates will require	separate scheduling and	may have ad	ditional co	Sts:

Good Faith Estimate Disclaimer

Starting a dispute resolution process will not reduce the quality of health services you receive at
If the agency reviewing your dispute ▶ Agrees with you: You will have to pay the price on this Good Faith Estimate. ▶ Disagrees with you: You will owe the higher amount on your bill.
If your bill is more than \$400 above the original Good Faith Estimate, you have the right to dispute charges by starting a provider-patient dispute resolution process . If you choose to use the dispute resolution process, you must start it within 120 calendar days (about 4 months) of the date on your original bill from There is a \$25 fee.
Right to Dispute Additional Charges If you have questions or concerns about your bill, please contact at and let them know your bill is higher than the amount in the Good Faith Estimate. They can answer questions about any differences and determine if your bill can be adjusted to align with the original Good Faith Estimate.
If you have question about this Good Faith Estimate: ➤ Contact: Contact to explain this estimate and answer any questions. They also can connect you with certain programs that may reduce or cover the cost of your health care. ➤ If you have health insurance, call your health insurance plan. Your plan may have better information about how much you'll be asked to pay. You also can ask about what's covered under your plan and your provider options.
This Good Faith Estimate is not a contract and does not require you to obtain services or items from or any of the other providers or facilities listed on this document.
The Good Faith Estimate does not include any unknown or unexpected costs. There may be additional charges if complications or special circumstances occur during your visit. If this happens, federal law allows you to dispute the bill using a dispute process.
This Good Faith Estimate details the costs of services and items that are expected for the appointment you scheduled (or may schedule in the future), as documented in this agreement. Estimated costs are based on information known by at the time the estimate was created. This Good Faith Estimate does not include additional, related services and items that may require separate scheduling or need to be requested separately.
Under Section 2799B-6 of the Public Health Service Act,

For more information about your rights and protections

or to start a dispute resolution process, visit www.cms.gov/nosurprises/consumers or call 1-800-985-3059.

Acknowledge	ement
With my signature, I acknowledge the receipt of a Go understand the information provided to me in this Go for services and my rights and protections. This is no	I further acknowledge that I od Faith Estimate, including cost estimates
Signature of patient or parent/guardian	Date
Name of patient or parent/guardian (printed)	Relationship to patient

Appendix D: Good Faith Estimate Scenarios and Examples

Scenario 1

An established patient schedules an appointment for removal of a copper intrauterine device (IUD) and insertion of a new copper IUD. The patient states they would like to discuss other contraceptive methods, specifically other long-acting r versible contraceptive (LARC) methods, during the appointment. Ultimately, they chooseto have an another copper IUD.

The patient is uninsured and, at their last visit, reported an income above 250% of the federal poverty level (FPL) and, therefore, is a fully self-pay patient. Based on the information provided, the following services and charges would be documented in the Good Faith Estimate (GFE):

Code	Description	ICD-10	Charge	Patient Contribution*= 100%
99213	E/M Visit (Est.)	Z30.09	\$30.00	\$30.00
58301	IUD Removal	Z30.433	\$49.00	\$49.00
58300	IUD Insertion	Z30.433	\$168.00	\$168.00
J3700	Copper IUD Kit	Z30.433	\$247.00	\$247.00
	TO	TAL COST	\$494.00	\$494.00

^{*}Patient contribution after any adjustments applied under the provider or facility's Financial Assistance Policy.

Completing the GFE:

- Prior to furnishing the GFE, the provider should confirm that the patient's income has not changed since their last visit. For this example, the patient's contribution would be 100% of the charge on the provider's sliding fee scale.
- The provider should complete the GFE form with anticipated diagnosis codes and the descriptions and costs of each known service, and use the sliding fee schedule rate based on the patient's confirmed income.
- Items included on the GFE:
 - E/M office visit: Based on the above scenario, the office visit level is listed as a Level 3 (99213). If the specific E/M level is unknown at the time the GFE is created, the provider should opt to include the higher level of service to avoid the possiblity of a higher charge than what the was quoted in the GFE.
- GFE disclaimer: Ensure that the patient is aware of the disclaimer statement in the GFE form. If the patient chooses an alternate form of contraception that is a higher cost than the IUD, they will be responsible for the difference in cost. A best practice to confirm patient understanding of the disclaimer is to have them sign the GFE form.

A new patient schedules an appointment for an initial visit and placement of a 3-year levonorgestrel-releasing IUD (Skyla). They are not using any contraceptive method at this time. After the procedure, a transvaginal ultrasound is required to check for correct position, as this was a difficult IUD placemen

The patient is uninsured and reports an income of 190% of FPL. With this income level, and based on the provider's sliding fee scale, the patient is eligible for a 50% discount.

Services and charges documented in the GFE:

Code	Description	ICD-10	Charge	Patient Contribution = 50%
99203	E/M Visit (New)	Z30.09	\$58.00	\$29.00
58300	IUD Insertion	Z30.430	\$168.00	\$84.00
J7301	Skyla Kit	Z30.430	\$249.00	\$124.50
	TO:	TAL COST	\$475.00	\$237.50

Actual services provided and total cost:

Code	Description	ICD-10	Charge	Patient Contribution = 50%
99203-25	E/M Visit (New)	Z30.09	\$58.00	\$29.00
58300	IUD Insertion	Z30.430	\$168.00	\$84.00
J7301	Skyla Kit	Z30.430	\$249.00	\$124.50
76830	Transvaginal Ultrasound	Z30.431	\$68.00	\$34.00
TOTAL COST			\$543.00	\$271.50

Completing the GFE:

- The GFE completed for this appointment is based on a patient whose reported income slides their contribution to 50% of charges. This contribution level may change based on information collected during the visit's income verification process.
- Items included on the GFE:
 - E/M office visit: Based on the above scenario, the office visit level is listed as a Level 3 (99203). If the specific E/M level is unknown at the time the GFE is created, the provider should opt to include the higher level of service to avoid the possibility of a higher charge than what the was quoted in the GFE.
 - Only the usual and customary costs associated with an IUD insertion and IUD insertion kit. Since it was unknown that an ultrasound would be required for the IUD placement, this item is not included in the GFE.

- GFE disclaimer: The patient can be charged for the additional ultrasound service as it was medically necessary but not anticipated at the time the GFE was completed.
- If billing a payer, the -25 modifier attached to the E/M code signifies that the initial visit to establish care in the practice and the IUD placement are separately identifiable services.

This example highlights the importance of reviewing the GFE disclaimer with patients, specifically text related to the possibility they will be charged for a medically necessary service or item that could not have reasonably been anticipated by the provider or facility, and then having them sign the GFE form to acknowledge understanding.

A 22-year old woman schedules a new patient appointment for a well woman visit. During the visit, the patient asks to discuss her contraceptive options, after which they decide they would like a contraceptive implant. An insertion is completed as part of the same visit.

The patient is uninsured and reports an income of 150% of FPL. With this income level, and based on the provider's sliding fee scale, the patient is eligible for a 75% discount (i.e., 25% contribution).

Services and charges documented in the GFE:

Code	Description	ICD-10	Charge	Patient Contribution = 25%
99385	Preventive Visit: 18-39 Years	Z01. 419	\$114.00	\$28.50
		TOTAL COST	\$114.00	\$28.50

Actual services provided and total cost:

Code	Description	ICD-10	Charge	Patient Contribution = 25%
99385-25	Preventive Visit: 18-39 Years	Z01. 419	\$114.00	\$28.50
11981	Implant Insertion	Z30.017	\$207.00	\$51.75
J7307	Implant Kit	Z30.017	\$415.00	\$103.75
		TOTAL COST	\$736.00	\$184.00

Completing the GFE:

- The GFE completed for this appointment is based on a patient whose reported income slides their contribution to 25% of eligible charges. This contribution level may change based on information collected during income verification.
- Items included on the GFE:
 - Well woman exam. If there are standard sceening labs ordered as part of this visit type (e.g., cervical cytology, HPV test, STI screening tests), these costs should be included as separate line items on the GFE.
 - GFE disclaimer: Since the discussion related to the patient's contraceptive options – and their ultimate decision to obtain a contraceptive implant – were unknown at the time the GFE was completed, the patient can be charged for the additional services not included on the GFE.
 - If billing a payer, the -25 modifier attached to the E/M code signifies that the well woman visit and the implant placement are separately identifiable services.

This example highlights the importance including clear and understandable language in the GFE's disclaimer and, if possible, reviewing the GFE form with patients so that they understand the potential for additional costs. This is especially true for preventive appointments, as there often are conditions and/or services performed that were unknown at the time of the GFE form was completed. It is a best practice is to have the patient sign the GFE form to acknowledge understanding.

An established patient schedules an appointment to review all contraception options. During the appointment, the patient determines they would like a copper IUD. The copper IUD is inserted as part of the same encounter.

The patient does not wish to use their health insurance coverage due to confidentiality concerns. They report an income of 160% of FPL. With this income level, and based on the provider's sliding fee scale, the patient is eligible for a 75% discount (i.e., 25% contribution).

Services and charges documented in the GFE:

Code	Description	ICD-10	Charge	Patient Contribution = 25%
99213	E/M Visit (Est.)	Z30.09	\$30.00	\$7.50
	List of contraceptive products	Various	See estimated cost schedule	See estimated cost schedule
			TOTAL COST	\$7.50 + supplies or prescriptions

Actual service provided and total cost:

Code	Description	ICD-10	Charge	Patient Contribution = 25%
99213-25	E/M Visit (Est.)	Z30.09	\$30.00	\$7.50
58300	IUD Insertion	Z30.430	\$125.00	\$31.25
J7300	Copper IUD Kit	Z30.430	\$247.00	\$61.75
		TOTAL COST	\$402.00	\$100.50

Completing the GFE:

- The GFE completed and signed for this appointment is based on a patient whose income slides their contribution to 25% of charges. This contribution level may change based on information collected during income verification.
- Items included on the GFE:
 - E/M office visit: Based on the above scenario, the office visit level is listed as a Level 3 (99213). If the specific E/M level is unknown at the time the GFE is created, the provider should opt to include the higher level of service to avoid the possiblity of a higher charge than what the was quoted in the GFE.
 - A range of costs associated with the different contraceptive options should be made available to the patient, including the cost of supplies and LARC insertion procedures.

- GFE disclaimer: Since the patient did not know what type of contraception they desired when scheduling their appointment, providing an estimated cost schedule based on currently available contraceptive options provides the patient with a reference point.
- The -25 modifier attached to the E/M code signifies to the payer that the contraceptive counseling and the implant placement are separately identifiable services.

This example highlights the value of reviewing the GFE and disclaimer with patients prior to completing and signing the GFE form. During this process, the health center should clarify that the GFE does not include the list of available contraceptive options on the cost schedule.

An established patient schedules an appointment for removal of their IUD, as they would like to start trying to become pregnant. They would also like pre-pregnancy advice at the time of this appointment.

The patient has an income below 100% of the FPL, but does not qualify for Medicaid. Accordingly, their contribution after adjustments applied under the health center's Financial Assistance Policy is 0%.

Services and charges documented in the GFE:

Code	Description	ICD-10	Charge	Patient Contribution = 0%
99214	E/M Visit (Est.)	Z31.61	\$38.00	\$0.00
58301	IUD Removal	Z30.430	\$49.00	\$0.00
		TOTAL COST	\$87.00	\$0.00

Actual services provided and total cost:

Code	Description	ICD-10	Charge	Patient Contribution = 0%
99214-25	E/M Visit (Est.)	Z31.61	\$38.00	\$0.00
58301	IUD Removal	Z30.430	\$49.00	\$0.00
		TOTAL COST	\$87.00	\$0.00

Completing the GFE:

- The GFE completed and signed for this appointment is based on a patient whose income slides their contribution to 0% of charges. This contribution level may change based on information collected during income verification.
- Items included on the GFE:
 - E/M office visit: Based on the above scenario, the office visit level is listed as a Level 4 (99214).
 - Coding and billing for the E/M visit on the same date as the IUD removal is appropriate, as this charge was for the time spent in pre-pregnancy counseling. Pre-pregnancy counseling is a "separately identifiable service" from the IUD removal and the level of the E/M visit is based on the greater of either total time or medical decision making. Otherwise, an E/M visit would not be billed if the sole purpose of the visit was the removal of the IUD.

 If billing a payer, the -25 modifier attached to the E/M code signifies that the contraceptive counseling and the IUD removal are separately identifiable services.

An established patient walks in for an appointment with a complaint of vaginal discharge. They would like to be examined and tested for sexually transmitted infections (STIs). They inform the front desk clerk that they do not have health insurance and they want to pay for their care out-of-pocket.

Since this is a walk-in appointment, a GFE is not required based on the NSA guidelines. However, since the patient has advised the health center that they are uninsured (self-pay), it is a best practice to provide an estimate of charges. This can be done by simlpy reviewing potential charges and associated costs or by completing a GFE form, which is standard and contains all of the necessary fields to pr vide a patient with estimated costs.

During the visit, evaluation of the vaginal discharge by microscopy showed bacterial vaginosis (BV). The clinician dispensed metronidazole 500 mg orally twice a day for 7 days (14 tablets).

Services and charges documented in the GFE:

Code	Description	ICD-10	Charge	Patient Contribution
99212	E/M Visit (Est.)	N89.8	\$18.00	\$18.00
87210	Point-of-care Microscopy	N89.8	\$8.00	\$8.00
87491	Chlamydia NAAT	Z20.2	\$31.00	\$31.00
87591	Gonorrhea NAAT	Z20.2	\$31.00	\$31.00
86592	Syphilis Test	Z20.2	\$4.00	\$4.00
86703	HIV 1+2	Z20.2	\$12.00	\$12.00
TOTAL COST			\$104.00	\$104.00

Actual services provided and total cost:

Code	Description	ICD-10	Charge	Patient Contribution
99212	E/M Visit (Est.)	N89.8	\$18.00	\$18.00
87210	Point-of-care Microscopy	N89.8	\$8.00	\$8.00
87491	Chlamydia NAAT	Z20.2	\$31.00	\$31.00
87591	Gonorrhea NAAT	Z20.2	\$31.00	\$31.00
86592	Syphilis Test	Z20.2	\$4.00	\$4.00
86703	HIV 1+2	Z20.2	\$12.00	\$12.00
	Metronidazole x 7 d	N76.0	\$8.00	\$8.00
TOTAL COST			\$112.00	\$112.00

Completing the GFE:

- The GFE completed and signed for this appointment is based on a patient who does not disclose their income information and expresses a desire to pay for services out-of-pocket. This contribution level may change if the patient provides income information.
- Items included on the GFE:
 - E/M office visit: Based on the above scenario, the office visit level is listed as a Level 2 (99212). If the specific E/M level is unknown at the time the GFE is created, the provider should opt to include the higher level of service.
 - GFE disclaimer: The patient can be charged for the metronidazole prescription as it was medically necessary but the patient's course of treatment was not known at the time the GFE was completed.
- Important note: If the STI tests are sent to a commercial lab that will bill the patient separately, the patient should not be charged for the tests by the provider or facility. In this case, the only charges collected by the health center should be for the E/M visit, point-of-care microscopy, and metronidazole. In these cases, estimated lab costs should still be included in the GFE, but listed under a "co-provider" field.

This example highlights the importance of reviewing the GFE disclaimer with patients, specifically text related to the possibility they will be charged for a medically necessary service or item that could not have reasonably been anticipated by the provider or facility, and then having them sign the GFE form to acknowledge understanding. It also serves as an examples of the requirement to include and review cost estimates for services (e.g., labs, prescriptions) that may be charged by co-provider or co-facility.

Implementing the No Surprises Act in Family Planning Settings

Appendix E: Guidance for Selected Dispute Resolution Entities: Required Steps to Making a Payment Determination under the PPDR Process

DEPARTMENT OF HEALTH AND HUMAN SERVICES



Guidance for Selected Dispute Resolution (SDR) Entities: Required Steps to Making a Payment Determination under the Patient-Provider Dispute Resolution (PPDR) Process

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1. General Information and Background

1.1 Background

Effective January 1, 2022, the No Surprises Act¹ (NSA) protects uninsured (or self-pay) individuals from many unexpectedly high medical bills. Providers and facilities will be required to furnish a good faith estimate of expected charges after an item or service is scheduled, or upon request. Throughout this document the term "providers" also includes providers of air ambulance services. The good faith estimate will include an enumerated list of items and services, grouped by each provider or facility, reasonably expected to be provided for the primary item or service, and items and services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care. Additionally, a new patient-provider dispute resolution (PPDR) process will be available for uninsured (or self-pay) individuals who get a bill for an item or service that is substantially in excess of the expected charges on the good faith estimate. Under the PPDR process, an uninsured (or self-pay) individual, or their authorized representative², may initiate the PPDR process for a determination about how much to pay a provider or facility for specific items or services. This process can provide important consumer protections for the uninsured (or self-pay) individual from billed charges that are substantially in excess of the expected charges in the good faith estimate.

An uninsured (or self-pay) individual is an individual who does not have health insurance 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 (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or an individual who has benefits for an item or service under a group health plan or individual or

¹ Enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260).

² Authorized representative means an individual authorized under State law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with a facility or an employee of a provider or facility represented

group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code, but does not seek to have a claim for such item or service submitted to such plan or coverage.

On October 7, 2021, HHS published in the Federal Register interim final rules (IFRs) titled *Requirements Related to Surprise Billing; Part II*,³ implementing various provisions of the NSA, including good faith estimates and the PPDR process for payment determinations.

1.2 Applicability

The requirements for health care providers and health care facilities related to the issuance of good faith estimates of expected charges for uninsured (or self-pay) individuals (or their authorized representatives), upon request or upon scheduling an item or service under 45 CFR 149.610 are generally applicable for good faith estimates requested on or after January 1, 2022 or for good faith estimates required to be provided in connection with items or services scheduled on or after January 1, 2022.

HHS recognizes that some providers or facilities may need to establish efficient and secure communication channels for transmission of good faith estimate information between convening providers or facilities and co-providers and co-facilities. A convening health care provider or convening health care facility is the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service. A co-provider or cofacility is a provider or facility that furnishes items or services that are customarily provided in conjunction with a primary item or service. It is also understood that it may take time for providers and facilities to develop systems and processes for receiving and providing the required information from co-providers and co-facilities. Therefore, for good faith estimates provided to uninsured (or self-pay) individuals from January 1, 2022 through December 31, 2022, HHS will exercise its enforcement discretion in situations where a good faith estimate provided to an uninsured (or self-pay) individual does not include expected charges from coproviders or co-facilities. A co-provider or co-facility is not prohibited from furnishing the information before December 31, 2022, and nothing would prevent the uninsured (or self-pay) individual from separately requesting a good faith estimate directly from the co-provider or cofacility, in which case the co-provider and co-facility would be required to provide the good faith estimate for such items or services. Otherwise during this period, HHS encourages convening providers and convening facilities to include a range of expected charges for items or services reasonably expected to be provided and billed by co-providers and co-facilities. To the extent states are the primary enforcer of these requirements, HHS encourages states to take a similar approach, and will not consider a state to be failing to substantially enforce these requirements if it takes such an approach from January 1, 2022 through December 31, 2022.

The IFR establish a PPDR process that is applicable to uninsured (or self-pay) individuals; providers, facilities, and providers of air ambulance services; and Selected Dispute Resolution (SDR) entities, beginning on or after January 1, 2022. More specifically, the PPDR process may

https://www.federalregister.gov/documents/2021/10/07/2021-21441/requirements-related-to-surprise-billing-part-ii.

be used for payment determination if the total billed charges (by the convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under 45 CFR 149.610.

The provisions regarding SDR entity certification under 45 CFR 149.620(a) and (d), are applicable beginning on October 7, 2021.

1.3 Purpose

The purpose of this document is to provide guidance to SDR entities on various aspects of the PPDR process. This document includes information about how uninsured (or self-pay) individuals may initiate the PPDR process and the general requirements of the PPDR Process. It also provides information about the selection process and criteria for SDR entities, the requirements SDR entities must follow when making payment determinations, guidance on confidentiality standards, record keeping requirements, the revocation of certification, as well as how parties should request an extension of time periods for extenuating circumstances. For a detailed overview of the PPDR process, see the visual below, "Patient-Provider Dispute Resolution Process Overview." Additional guidance may be developed in the future to address specific questions or scenarios submitted by SDR entities.

PPDR Process Overview

TIMELINE

SUMMARY OF STEPS

Preceding the PPDR Process:

Start:

An uninsured (or self-pay) individual receives a bill from a provider or facility that is substantially in excess of their good faith estimate (i.e., \$400 or greater than the good faith estimate for that provider or facility).

Within 120 calendar days

Initiation Notice and Administrative Fee

The uninsured (or self-pay) individual (or their authorized representative) submits the initiation notice, and other relevant information to HHS. HHS will choose and notify a Selected Dispute Resolution (SDR) Entity. Once HHS has chosen the SDR entity, the uninsured (or self-pay) individual must pay an administrative fee to the SDR entity. The initiation notice must be sent within 120 calendar days from the date on the initial bill.

Within 3 **business** days

SDR Entity Conflict of Interest Identification

Once the SDR entity is chosen, the SDR entity may attest to having a conflict of interest with the uninsured (or selfpay) individual and the provider or facility. Should a conflict of interest exist, HHS will select a new SDR entity to conduct the PPDR process. If no SDR entities are available to resolve the dispute, the initially-selected SDR entity will be required to initiate their entity-level conflict of interest mitigation plan, (which may include identifying a subcontractor whom they have verified does not have a conflict of interest) and submit notice to HHS related to the implementation of the mitigation plan. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed. In the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity.

21 calendar days

Eligibility Determination and Additional Information

PPDR Process:

After the SDR entity receives the information submitted by the uninsured (or self-pay) individual, the SDR entity will notify the uninsured (or self-pay) individual about their eligibility to use the PPDR process or if additional information is needed to determine eligibility. If additional information is required, the uninsured (or self-pay) individual has 21 calendar days to furnish it after being notified of the information deficiency.

PPDR Initiation

Start:

If the SDR entity determines that the item or service meets the eligibility criteria, and the initiation notice contains the required information, the SDR entity will notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity, and that the item or service has been determined eligible for dispute resolution.

Within 3 business days

Parties' Conflict of Interest Identification

The uninsured (or self-pay) individual and provider or facility may attest to having a conflict of interest with the SDR entity. Should a conflict of interest exist, the SDR entity must notify HHS within 3 business days of receiving the attestation. HHS will select a different entity to conduct the PPDR process.

Within 10 business days

Provider or Facility Submits Information

The provider or facility should submit required information to the SDR entity within 10 business days of receipt of the selection notice. This required information includes: 1) A copy of the good faith estimate, 2) A copy of the billed charges, and 3) If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances

Within 30 business days

Patient-Provider Negotiation

If the parties to a dispute resolution process agree on a payment amount (through either an offer of financial assistance or an offer of a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full) after the PPDR process has been initiated but before the date on which a determination is made, the provider or facility will notify the SDR entity through the federal IDR Portal, electronically, or in paper form as soon as possible, but no later than 3 business days after the date of the agreement.

Payment Determination by the SDR Entity

No later than 30 business days after receipt of the information requested from the provider or facility, the SDR entity must make a determination regarding the amount to be paid by the uninsured (or self-pay) individual, taking into account the requirements of the PPDR payment determination process. The SDR entity should inform both parties of this determination as soon as practicable after reaching a payment determination.

2. Initiating the Patient-Provider Dispute Resolution Process

2.1 Timeframe

An uninsured (or self-pay) individual (or their authorized representative) may initiate the PPDR process by submitting an **Initiation Notice** via the Federal IDR portal, electronic or postal mail to HHS within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate.

The initiation date of the PPDR process is the date that HHS receives the **Initiation Notice**. The online Federal IDR portal will display the date on which the Initiation Notice has been received by HHS.

In addition, the uninsured (or self-pay) individual must submit an administrative fee to the SDR entity in an amount and manner specified by HHS in PPDR fee guidance.

2.2 Delivery of the Initiation Notice

The **Initiation Notice** sent by the uninsured (or self-pay) individual (or their authorized representative) must be submitted to HHS:

- through the online Federal IDR portal,
- electronically (such as email), or
- on paper through the mail.

2.3 Notice Content

The **Initiation Notice** must include:

- Information sufficient to identify the item or service under dispute, including:
 - o The date the item or service was provided; and
 - o A description of the item or service.
- A copy of the provider or facility bill for the item and service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);
- A copy of the good faith estimate for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);
- If not included on the good faith estimate, contact information of the provider or facility involved, including, if available:
 - o Name:
 - o Email address:
 - o Phone number; and
 - o Mailing address.
- The State where the items or services in dispute were furnished; and
- The uninsured (or self-pay) individual's contact information and communication preference:
 - o Name;

- o Phone number;
- o Mailing Address;
- o Email;
- o Communication preference: Electronic mail (e-mail), paper mail, or phone.

3. PPDR Process Following Initiation: Selection of the SDR Entity

3.1 Timeframe

Upon receiving the **Initiation Notice** for the PPDR process from an uninsured (or self-pay) individual, HHS will select one of the contracted SDR entities to conduct the PPDR process.

3.2 Selected SDR Entity Responsibilities After Selection

After the SDR entity is selected by HHS, the SDR entity may attest that a conflict of interest exists, as described below in section 3.2.1. If no conflicts of interest exist, the SDR entity must notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity through the **Notice of SDR Entity Selected by HHS**, described in section 3.4 of this guidance.

If either party to the PPDR process, the uninsured (or self-pay) individual, or the provider or facility, attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, the SDR entity must notify HHS within **three business days** after receiving the attestation. Should a conflict of interest exist, HHS will then select a new SDR entity to conduct the PPDR process for the item or service. In the event that no SDR entities are available to resolve the dispute, the initially-selected SDR entity will be required to initiate their entity-level conflict of interest mitigation plan, which may include identifying a sub-contractor whom they have verified does not have conflicts of interest. HHS will then assign the case to the identified sub-contractor to conduct the PPDR process for the item or service in dispute.

3.2.1 Conflicts of Interest

An SDR entity must not have any conflicts of interest with respect to a party to a payment determination. Specifically, the SDR entity cannot have with respect to a party to the payment determination a material relationship, status, or condition of the party that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. In accordance with 45 CFR 149.620(e)(3), a conflict of interest exists when an SDR entity is:

- A provider or a facility;
- An affiliate or a subsidiary of a provider or facility;
- An affiliate or subsidiary of a professional or trade association representing a provider or facility; or
- An SDR entity, or any personnel assigned to a determination has a material familial, financial, or professional relationship with a party to the payment determination being

disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute.

3.3 Validation of Initiation Notice

After selection by HHS, the SDR entity will review the **Initiation Notice** to ensure the items or services in dispute meet the eligibility criteria described in 45 CFR 149.620(b) and that the **Initiation Notice** contains the required information described in Section 2 of this guidance. If the SDR entity determines that the item or service meets the eligibility criteria, and the **Initiation Notice** contains the required information, the SDR entity will notify the uninsured (or self-pay) individual and the provider or facility that the item or service has been determined eligible for dispute resolution by sending the **Notice of SDR Entity Selected by HHS** as described in section 3.4 of this guidance.

If the SDR entity determines that the item or service does not meet the eligibility criteria or that the **Initiation Notice** is incomplete, the SDR entity will provide an **Insufficient Notice** to the uninsured (or self-pay) individual of the determination and the reasons for the determination and will notify the uninsured (or self-pay) individual that they may submit supplemental information, postmarked within 21 calendar days, to resolve any deficiencies identified. If the **Insufficient Notice** is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar-day extension will be granted so that the individual will have a total of 35 calendar days to submit supplemental information.

3.4 Notice of Selected Dispute Resolution Entity Selected by HHS

Once HHS selects an SDR entity, the SDR entity will, through the Federal IDR portal, or electronic or paper mail, or phone, send the **Notice of SDR Entity Selected by HHS** to the uninsured (or self-pay) individual, and to the provider or facility to notify that a PPDR initiation notice has been received and is under review. Such notice shall also include:

- Contact information for the SDR entity including:
 - o The SDR entity's name assigned to the case;
 - Mailing address;
 - o Phone number; and
 - o Fax number.
- PPDR case reference number;
- Sufficient information to identify the item or service under dispute;
- The date the initiation notice was received;
- Notice of the additional requirements for providers or facilities while the PPDR process is pending including:
 - Prohibition on moving the bill for the disputed item or service into collection or threatening to do so;
 - o Ceasing collection efforts if the bill has already moved into collection;
 - o Requirements to suspend the accrual of any late fees on unpaid bill amounts until after the PPDR process has concluded; and

- Prohibition on taking or threatening to take any retributive action against an uninsured (or self-pay) individual for utilizing the PPDR process to seek resolution for a disputed item or service.
- Information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist the individual with the dispute such as authorized representatives from state Consumer Assistance Programs (CAPs) or legal aid organizations;
- Request for the provider or facility to submit to the SDR entity, through the online Federal IDR portal:
 - A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);
 - A copy of the billed charges provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and
 - O If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.
- And, the SDR entity's confirmation that they have no conflicts of interest for the case, meaning they:
 - O not have a financial interest in this case and are not an employee of the health care provider, facility, or patient;
 - O Did not have a familial, financial, or professional relationship with the health care provider, facility, or patient within the last year; nor
 - Do not have another conflict of interest with the health care provider, facility, or patient.

4. Notice to Provider or Facility

4.1 Information Needed from the Provider or Facility

No later than 10 business days after the receipt of the Notice of SDR Entity Selected by HHS the provider or facility must submit to the SDR entity:

- A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);
- A copy of the billed charges provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and
- If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances that could not have

reasonably been anticipated by the provider or facility when the good faith estimate was provided.

4.2 Manner of Submission

HHS strongly recommends that the information requested in Section 4.1 be submitted through the online <u>Federal IDR portal</u> to help ensure timely and secure processing. This information may also be submitted through alternative means, such as paper or electronic mail.

5. Extension of Time Periods for Extenuating Circumstances

Many of the time periods for the PPDR process may be extended in the case of extenuating circumstances at HHS's discretion.

- Time periods for payments can NOT be extended: The timing of all payments, including payment of the administrative fee to SDR entities cannot be extended. All other time periods are eligible for an extension at the HHS's discretion.
- What qualifies as "extenuating circumstances" for an extension: HHS may extend time periods on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such extension may be necessary if, for example, a natural disaster impedes efforts by providers, or facilities to comply with time period requirements.
- Required Attestation of Prompt Action: For the extension to be granted, the parties must attest that prompt action will be taken to ensure that the dispute determinations are made as soon as administratively practicable.
- How to request an extension: Parties may request an extension, and provide applicable attestations, by submitting a Request for Extension due to Extenuating Circumstances through the online Federal IDR portal, or electronic or paper mail, (if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause) including an explanation about the extenuating circumstances that require an extension and why the extension is needed.
- When to request an extension: A request for an extension can be filed at any time, either before or after a deadline, and HHS will consider the request and may grant the extension. However, requesting an extension does not stop the PPDR process and all of its timelines unless and until the extension is granted, so parties should continue to meet deadlines to the extent possible.

6. Payment Determination

6.1 Timeframe

No later than 30 business days after receipt of the information requested in the Notice of SDR Entity Selected by HHS, the SDR entity must make a determination regarding the amount to be paid by the uninsured (or self-pay) individual, taking into account the requirements in section 6.2.

6.2 Payment Determination

When making a payment determination the SDR entity must:

- Review any documentation submitted by the uninsured (or self-pay) individual, and the provider or the facility;
- Make a separate determination for each unique item or service charged as to whether the provider or facility has provided credible information to demonstrate that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service; and
- Make a determination of whether the difference between the billed charge and the expected charge for the item or service in the good faith estimate is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

6.2.1 For an Item or Service that Appears on the Good Faith Estimate:

- If the billed charge is equal to or less than the expected charge for the item or service in good faith estimate, the SDR entity must determine the amount to be paid for the item or service as the billed charge.
- If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility does not provide credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid for the item or service to be equal to the expected charge for the item or service in the good faith estimate.
- If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility provides credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith

estimate was provided, the SDR entity must determine as the amount to be paid for the item or service, the lesser of:

- o The billed charge; or
- o The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area, generally meaning one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State, and for air ambulance services generally meaning - one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605), where the services were provided, that is reflected in an independent database. An independent database is defined as a State's all-payer claims database or any third-party database using the methodology described in 45 CFR 149.140(c)(3), except that in cases where the amount determined by an independent database is determined to be less than the expected charge for the item or service listed on the good faith estimate, the amount to be paid will be the expected charge for the item or service listed on the good faith estimate. When comparing the billed charge with the amount contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

6.2.2 For an Item or Service that does not Appear on the Good Faith Estimate (new item or service):

- If the SDR entity determines that the information submitted by the provider or facility does not provide credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine that amount to be paid for the new item or service to be equal to \$0.
- If the SDR entity determines that the information submitted by the provider or facility provides credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid for the new item or service, the lesser of:
 - o The billed charge; or
 - The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area, generally meaning one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State,

and one region consisting of all other portions of the State, and for air ambulance services generally meaning - one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605), where the services were provided, that is reflected in an independent database. An independent database is defined as a State's all-payer claims database or any third-party database using the methodology described in 45 CFR 149.140(c)(3). When comparing the billed charge with the amounts contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

6.2.3 Calculation of the Final Payment Amount

To calculate the final payment determination amount, the SDR entity must add together the amounts to be paid for all items or services subject to the determination. In cases where the final amount determined by the SDR entity is lower than the billed charges, the SDR entity must reduce the total amount determined by the amount paid by the individual for the administrative fee to calculate the final payment amount to be paid by the individual for the items or services.

6.2.4 Written Payment Determination

Once the final payment amount has been calculated, the SDR entity should, as soon as practicable, inform the uninsured (or self-pay) individual and the provider or facility, through the online Federal IDR portal, or by electronic or paper mail, of such determination, the determination amount and the SDR entity's justification for making the determination. After the **SDR Determination Notice to Parties** is sent, the SDR entity will close the case.

6.2.5 Effects of Determination

A determination made by an SDR entity will be binding upon the parties involved, unless there is evidence of fraud or misrepresentation of the facts presented to the selected SDR entity regarding the claim. A determination may not be binding in the following circumstances:

- If the provider or facility chooses to offer the uninsured (or self-pay) individual financial assistance; or
- If the provider or facility agrees to accept an offer for a lower payment amount than the SDR entity's determination; or
- If the uninsured (or self-pay) individual agrees to pay the billed charges in full; or
- If the uninsured (or self-pay) individual and the provider or facility agree to a different payment amount.

7. Recordkeeping and Reporting Requirements

6-year recordkeeping requirement: SDR entities must maintain records of relevant documentation associated with any payment determination for **6 years**. These records must be

available upon request, to the parties to the dispute, or to a State or Federal oversight agency, except when disclosure is not permitted under State or Federal privacy law.

Mandatory monthly reporting by certified SDR entities: Certified SDR entities, are contracted with HHS to conduct payment determinations as part of the federal PPDR process. As part of this contract agreement, certified SDR entities are required to submit data on the PPDR process.

Each certified SDR entity will be required to report various data related to the PPDR process and outcomes within **15 calendar days** after the close of each month.

HHS expects that many of these reporting requirements will be captured through the online Federal IDR portal, and HHS does not intend for certified SDR entities to report duplicative information. HHS will provide additional guidance to certified SDR entities on their specific reporting obligations.

8. PPDR Process Administrative Fee

8.1 Administrative Fee

In setting the administrative fee for 2022, HHS considered expected costs to HHS for operating the PPDR program, including contractor costs, and costs to HHS for utilizing the Federal IDR portal for PPDR cases. Due to the requirements in PHS Act section 2799B-7 that such an administrative fee must not pose a burden for uninsured (or self-pay) individuals to participate in the PPDR process, HHS will limit the amount of the administrative fee to \$25 for the calendar year beginning January 1, 2022, to be imposed on the non-prevailing party (providers, facilities, and uninsured (or self-pay) individuals) to the PPDR process. HHS believes this amount will allow HHS to offset some of the costs of operating the PPDR process while keeping the administrative fee sufficiently low to ensure uninsured (or self-pay) individuals are able to access the PPDR process.

Under the *Requirements Related to Surprise Billing; Part II*, an uninsured (or self-pay) individual (i.e., the initiating party) may initiate the PPDR process by submitting an initiation notice to the Secretary of HHS and paying the administrative fee to the SDR entity once the Secretary assigns one. In cases in which the uninsured (or self-pay) individual prevails in dispute resolution, the SDR entity would apply a reduction equal to the administrative fee paid by the individual to the final determination amount to be paid by the individual for the items or services. In cases where the provider or facility prevails in dispute resolution, the SDR entity would not reduce the final payment amount.

In the event that the parties agree to settle on a payment amount after initiation of the PPDR process, but before a payment determination is made, the provider or facility must notify the SDR entity through the online Federal IDR portal, electronically, or in paper form, as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notice must document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount that is **equal to at least half the amount of the administrative**

fee. Once the SDR entity receives the notification of the settlement, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply. Any administrative fees collected by the SDR entity but not yet paid to the Secretary of HHS at the time the SDR entity closes the dispute resolution case must be remitted to HHS upon receiving an invoice by HHS.

The amount of the administrative fee charged to the non-prevailing party may change in future years, but any such change will be promulgated in advance by additional guidance. For more information on the PPDR administrative fee see PPDR fee guidance.

8.2 Failure to Pay the Administrative Fee

If the initiating party does not pay the administrative fee, their claim will not enter the PPDR process.

9. Confidentiality Requirements

While conducting the PPDR process, certified SDR entities will be entrusted with individually identifiable health information (IIHI). SDR entities will be assessed on whether they meet the applicable certification requirements during the contracting process with HHS and such process will be separate and distinct from the certification process applicable to independent dispute resolution (IDR) entities that will provide IDR services for providers, providers of air ambulance services, facilities, plans and issuers as required under 26 CFR 54.9816-8T and 54.9817-2T, 29 CFR 2590.716-8 and 2590.717-2, and 45 CFR 149.510, and 45 CFR 149.520. Although an SDR entity may apply for certification as an IDR entity, SDR entities are not required to do so. However, consistent with the statutory requirement, SDR entities will be required to meet many of the same confidentiality requirements as certified IDR entities.

9.1 Privacy

The certified SDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and use IIHI to perform its required duties.

9.2 Security

Certified SDR entities are required to maintain the security of the IIHI they obtain by: ensuring the confidentiality of all IIHI they create, obtain, maintain, store, and transmit; protecting against any reasonably anticipated threats or hazards to the security of IIHI; protecting against any reasonably anticipated unauthorized uses or disclosures of IIHI; and by ensuring compliance by any of their personnel who have access to IIHI, including their contractors and subcontractors (as applicable).

Certified SDR entities are required to have policies and procedures in place to properly use and disclose IIHI, identify when IIHI should be destroyed or disposed of, properly store and maintain confidentiality of IIHI that is accessed or stored electronically, and identify the steps the certified

SDR entities will take to prevent, detect, contain, and correct security violations in the event of a breach regarding IIHI.

Certified SDR entities must securely destroy or dispose of IIHI in an appropriate and reasonable manner six years from either the date of its creation or the first date on which the certified SDR entity had access to it, whichever is earlier. In determining what is appropriate and reasonable, certified SDR entities should assess potential risks to the parties' privacy, as well as consider such issues as the form, type, and amount of IIHI to be disposed of. In general, examples of proper disposal methods may include: shredding, burning, pulping, or pulverizing paper records so that IIHI is rendered unreadable, indecipherable, and otherwise cannot be reconstructed; and, for IIHI contained on electronic media, clearing (using software or hardware products to overwrite media with non-sensitive data), purging (degaussing or exposing the media to a strong magnetic field in order to disrupt the recorded magnetic domains), or destroying the media (disintegration, pulverization, melting, incinerating, or shredding) may be reasonable methods of disposal.

When IIHI is stored by the certified SDR entity, the certified SDR entity must periodically review, assess, and modify the security controls implemented and mitigate related system risks to ensure the continued effectiveness of those controls and the protection of IIHI.

Certified SDR entities must develop and utilize secure electronic interfaces when transmitting IIHI electronically, including through data transmission through the online Federal IDR portal, and between disputing parties and the certified SDR entity during the PPDR process.

The certified SDR entity must implement policies and procedures: for guarding against, detecting, and reporting malicious software; for monitoring log-in attempts and reporting discrepancies; for creating, changing, and safeguarding passwords; and for electronic information systems that maintain IIHI to allow access only to those persons or software programs that have been granted access rights. All confidentiality requirements applicable to IDR entities also apply to certified SDR entities' contractors and subcontractors performing any duties related to the PPDR process with access to IIHI. For example, if a breach occurs, the contractor or subcontractors should notify the certified SDR entity to inform them of the risk assessment results, and the certified SDR entity must notify HHS and affected individuals as required under the IFR.

9.3 Breach and Incident Notification

SDR entities must report any actual or suspected breach of unsecured IIHI to the CMS IT Service Desk by telephone at (410) 786-2580 or 1-800-562-1963 or via email notification at cms_it_service_desk@cms.hhs.gov and <u>ACASecurityandPrivacy@cms.hhs.gov</u> within 24 hours from discovery of the breach. Incidents must be reported to the CMS IT Service Desk by the same means as breaches within 72 hours from discovery of the actual or suspected incident⁴.

⁴ For purposes of this guidance, "security incident" or "incident" has the meaning contained in OMB Memoranda M 17-12 (January 3, 2017) and means an occurrence that, in relation to the SDR's Entity's information technology system that stores and maintains unsecured IIHI: (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or the information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.

Following the discovery of a breach or potential breach of unsecured IIHI, the certified SDR entity must notify the applicable provider or facility; and HHS, as applicable.

If an actual or attempted acquisition, access, use, or disclosure of unsecured IIHI in a manner not permitted under 26 CFR 54.9816-8T(e)(2)(v), 29 CFR 2590.716-8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) is discovered, the certified SDR entity must conduct a risk assessment to determine the probability that the security or privacy of IIHI has been compromised based on, at least: the nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification; the unauthorized person who used the IIHI or to whom the disclosure was made; whether the IIHI was actually acquired or viewed; and the extent to which the risk to the IIHI has been mitigated. In addition, a breach must be treated as discovered by the certified SDR entity as of the first day on which such breach is known to the certified SDR entity or, by exercising reasonable diligence, should have been known to the certified SDR entity. A certified SDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence should have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified SDR entity.

The certified SDR entity must notify HHS of the potential or actual breach and provide to HHS in written form through the online Federal IDR portal its risk assessment determination as to whether any actual or suspected breach of unsecured IIHI, occurred within five business days from discovery of the breach, and whether there is likely a high or low probability this breach occurred. Further, the certified SDR entity must notify the CMS IT Service Desk by telephone at (410) 786-2580 or 1-800-562-1963 or via email notification at cms_it_service_desk@cms.hhs.gov and ACASecurityandPrivacy@cms.hhs.gov, regarding its risk assessment determination as to whether any actual or suspected breach of unsecured IIHI occurred within five business days from discovery of the breach, and whether there is likely a high or low probability this breach occurred.

9.4 Timing, Form, and Manner of Breach Notification

If an actual or attempted acquisition, access, use, or disclosure of unsecured IIHI in a manner not permitted under 26 CFR 54.9816-8T(e)(2)(v), 29 CFR 2590.716-8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) is discovered and the certified SDR entity finds there is a high probability that the security or privacy of unsecured IIHI has been compromised based on a risk assessment as described in 26 CFR 54.9816-8T(a)(2)(ii)(B), 29 CFR 2590.716-8(a)(2)(ii)(B), and 45 CFR 149.510(a)(2)(ii)(B), the certified SDR entity must provide notification to HHS of the breach or potential breach, without unreasonable delay and in no case later than 60 calendar days after the discovery of the breach or potential breach; the provider or facility, as applicable; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach.

The notice must include, to the extent possible: the identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified SDR entity to have been, subject to the breach; a brief description of the breach, including the date of the breach and the date of the discovery of the breach, if known; a description of the types of unsecured IIHI that were involved in the breach (for example, whether full name, Social Security number, date of

birth, home address, account number, diagnosis, disability code, or other types of information were involved); a brief description of what the certified SDR entity is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

Finally, a certified SDR entity must share the results of any risk assessment, including the probability that the security or privacy of IIHI has been compromised, with HHS.

Appendix A – Definitions

- (1) "Authorized representative" means an individual authorized under State law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with a facility or an employee of a provider or facility represented in the good faith estimate, unless such provider or employee is a family member of the uninsured (or self-pay) individual.
- (2) "Billed charge(s)" means the amount billed by a provider or facility for an item or service.
- (3) "*Conflict of interest*" means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when an SDR entity is:
 - o A provider or a facility;
 - o An affiliate or a subsidiary of a provider or facility;
 - An affiliate or subsidiary of a professional or trade association representing a provider or facility; or
 - O An SDR entity, or any personnel assigned to a determination has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute.
- (4) "Convening health care provider or convening health care facility (convening provider or convening facility)" means the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service.
- (5) "Co-health care provider or co-health care facility (co-provider or co-facility)" means a provider or facility other than a convening provider or a convening facility that furnishes items or services that are customarily provided in conjunction with a primary item or service.
- (6) "Credible Information" means information that, upon critical analysis, is worthy of belief and is trustworthy.
- (7) "Good faith estimate" means a notification of expected charges for a scheduled or requested item or service, including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

- (8) "Health care facility (facility)" means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing.
- (9) "Health care provider (provider)" means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, including a provider of air ambulance services.
- (10) "*Items and services*" 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.
- (11) "*Material familial relationship*" means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.
- (12) "Material financial relationship" means any financial interest of more than five percent of total annual revenue or total annual income of a SDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by an SDR entity to conduct or participate in any review in the PPDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.
- (13) "*Material professional relationship*" means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the SDR entity or any officer or director of the SDR entity.
- (14) "Service code" means the code that identifies and describes an item or service using the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG), or National Drug Code (NDC) code sets.
- (15) "Substantially in excess" means, with respect to the total billed charges by a provider or facility, an amount that is at least \$400 more than the total amount of expected charges listed on the good faith estimate for the provider or facility.

(16) "*Total billed charge(s)*" means the total of billed charges, by a provider or-facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

(17) "Uninsured (or self-pay) individual" means:

- o 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 (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or
- O An individual who has benefits for such item or service under a group health plan, or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage.

Appendix B – State-Federal Interaction

General Information

If HHS determines that a state law provides a process to determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility, and that such process meets or exceeds the requirements of the federal PPDR process, HHS shall defer to the State process and direct any patient-provider dispute resolution requests received from uninsured (or self-pay) individuals in such state to the State process to adjudicate the dispute resolution initiation request.

Minimum Federal requirements

A State process described in the above paragraph shall at a minimum:

- Be binding, unless the provider or facility offer for the uninsured (or self-pay) individual to pay a lower payment amount than the determination amount;
- Take into consideration a good faith estimate that meets the minimum standards established in <u>45 CFR 149.160</u>, provided by the provider or facility to the uninsured (or self-pay) individual;
- o If the State has a fee charged to uninsured (or self-pay) individuals to participate in the patient-provider dispute resolution process, the fee must be equal to or less than the Federal administrative fee; and
- Have in place conflict-of-interest standards that at a minimum meets the federal requirements.

HHS determination of State process

HHS will review the State process to determine whether it meets or exceeds the minimum Federal requirements. HHS will notify the state in writing of such determination.

HHS annual review of State process

HHS will review changes to the State process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards set forth in this section.

State process termination

In the event that the State process is terminated, or HHS determines that the State process no longer meets the minimum Federal requirements, HHS will make the Federal process available to uninsured (or self-pay) individuals in that State to ensure that the state's residents have access to a patient-provider dispute resolution process that meets the minimum Federal requirements.

Appendix C – Summary of the Patient-Provider Dispute Resolution (PPDR) Process

TIMELINE	PROCESS STEP
	Before the Patient-Provider Dispute Resolution (PPDR) Process:
Within 120 calendar days	1. Initiation Notice and Administrative Fee: the uninsured (or self-pay) individual submits the initiation notice and other relevant information to the Secretary of the Department of Health and Human Services (HHS). The initiation notice must be sent within 120 calendar days from when
	the uninsured or (self-pay) individual received their initial bill for items and services from their provider or facility. HHS will choose and notify the Selected Dispute Resolution Entity (SDR)
	entity). Once HHS has chosen the SDR entity, the uninsured (or self-pay) individual must pay an administrative fee to the SDR entity.
Within 3 business	2. SDR Entity Conflict of Interest Identification: Should a conflict of
days	interest exist, HHS will select a new SDR entity to conduct the PPDR Process. If no SDR entities are available to resolve the dispute, the initially-selected SDR entity will be required to initiate their entity-level
	conflict of interest mitigation plan, (which may include identifying a sub- contractor whom they have verified does not have a conflict of interest) and submit notice to HHS related to the implementation of the mitigation
	plan, no later than 3 business days following selection by HHS. HHS will then assign the case to the identified alternative SDR entity to conduct the PPDR process.
Within 21 calendar days	3. Eligibility Determination and Additional Information: After the SDR entity receives information submitted by the uninsured or (self-pay) individual, it will notify them regarding:
	- Whether or not they are eligible for PPDR
	- If additional information is needed to determine eligibility or if
	the patient can proceed to dispute resolution If additional information is required, the patient has 21 calendar days to
	furnish it after being notified of the information deficiency.
PPDR Process:	
	4. PPDR Initiation: If the SDR entity determines that the item or service meets the eligibility criteria, and the initiation notice contains the required information, the SDR entity will notify the uninsured (or self-pay) individual and the provider or facility that the item or service has been determined eligible for dispute resolution.
Within 3 business days	5. Parties' Conflict of Interest Identification: The uninsured (or self-pay) individual and provider or facility may attest to having a conflict of interest with the SDR entity. Should a conflict of interest exist, the SDR entity must notify HHS within <i>3 business days</i> of receiving the attestation. HHS will select a different entity to conduct the PPDR process.

TIMELINE	PROCESS STEP
	Before the Patient-Provider Dispute Resolution (PPDR) Process:
Within 10 business days	 6. Provider or Facility Submits Information: The provider or facility should submit any required information to the SDR entity within 10 business days of receipt of the selection notice. This information includes: A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the item or service under dispute A copy of the billed charges provided to the uninsured (or self-pay) individual for the item or service under dispute If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances
Within 3 business	7. Patient-Provider Negotiation: If the parties to a PPDR process agree on
days	a payment amount (through either an offer of financial assistance or an offer of a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full) after the PPDR process has been initiated but before the date on which a determination is made, the provider or facility will notify the SDR entity through the Federal IDR portal, electronically, or in paper form as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date of such settlement, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount equal to at least half the amount of the administrative fee paid.
Within 30 business	8. Payment Determination for PPDR by the SDR Entity: No later than
days	30 business days after receiving the required information from the provider or facility, the SDR entity must make a determination regarding the amount to be paid by the uninsured (or self-pay) individual, taking into account the requirements of the PPDR payment determination process. The SDR entity should inform both parties of this determination as soon as practicable after reaching a payment determination. The determination made by the SDR entity will be binding upon the parties involved, in the absence of fraud or evidence of misrepresentation of facts presented to the selected SDR entity regarding the claim, except that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, the uninsured (or self-pay) individual may agree to pay the billed charges
	in full, or the uninsured (or self-pay) individual and the provider or
	facility may agree to a different payment amount.
Time Period	Extenuating Circumstances: The parties may request extensions to most
Extensions	of the time periods above in cases of extenuating circumstances.

Appendix D – Other Resources

Model Notices available here

IDR portal available here

Other PPDR Guidance

- Guidance on Good Faith Estimates and the Patient-Provider Dispute Resolution (PPDR) process for people without insurance or who plan to pay for the costs themselves
- Guidance on Good Faith Estimates and the Patient-Provider Dispute Resolution (PPDR)
 Process for Providers and Facilities as Established in Surprise Billing, Part II; Interim Final Rule with Comment Period
- <u>Calendar Year 2022 Fee Guidance for the Federal Patient-Provider Dispute Resolution</u>
 (PPDR) Process Established in Surprise Billing, Part II; Interim Final Rule with Comment
 Period

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