



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

1.	General Information and Background	2
1.1	Background	2
1.2	Applicability	3
1.3	Purpose.....	4
2.	Initiating the Patient-Provider Dispute Resolution Process.....	6
2.1	Timeframe	6
2.2	Delivery of the Initiation Notice.....	6
2.3	Notice Content.....	6
3.	PPDR Process Following Initiation: Selection of the SDR Entity	7
3.1	Timeframe	7
3.2	Selected SDR Entity Responsibilities After Selection.....	7
3.3	Validation of Initiation Notice	8
3.4	Notice of Selected Dispute Resolution Entity Selected by HHS.....	8
4.	Notice to Provider or Facility.....	9
4.1	Information Needed from the Provider or Facility.....	9
4.2	Manner of Submission.....	10
5.	Extension of Time Periods for Extenuating Circumstances.....	10
6.	Payment Determination.....	11
6.1	Timeframe	11
6.2	Payment Determination.....	11
6.2.1	For an Item or Service that Appears on the Good Faith Estimate:	11
6.2.2	For an Item or Service that does not Appear on the Good Faith Estimate (new item or service):.....	12
6.2.3	Calculation of the Final Payment Amount	13
6.2.4	Written Payment Determination	13
6.2.5	Effects of Determination.....	13
7.	Recordkeeping and Reporting Requirements	13
8.	PPDR Process Administrative Fee	14

8.1	Administrative Fee.....	14
8.2	Failure to Pay the Administrative Fee	15
9.	Confidentiality Requirements.....	15
9.1	Privacy	15
9.2	Security	15
9.3	Breach and Incident Notification.....	16
9.4	Timing, Form, and Manner of Breach Notification.....	17
	Appendix A – Definitions	19
	Appendix B – State-Federal Interaction	22
	Appendix C – Summary of the Patient-Provider Dispute Resolution (PPDR) Process.....	23
	Appendix D – Other Resources.....	25

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 co-facility 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 co-providers 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 co-facility, 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

³ <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	<p style="text-align: center;">Initiation Notice and Administrative Fee</p> <p>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 <i>120 calendar days</i> from the date on the initial bill.</p>
Within 3 business days	<p style="text-align: center;">SDR Entity Conflict of Interest Identification</p> <p>Once the SDR entity is chosen, the SDR entity may attest to having a conflict of interest with the uninsured (or self-pay) 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 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. 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.</p>
21 calendar days	<p style="text-align: center;">Eligibility Determination and Additional Information</p> <p>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 <i>21 calendar days</i> to furnish it after being notified of the information deficiency.</p>
<i>PPDR Process:</i>	
Start:	<p style="text-align: center;">PPDR Initiation</p> <p>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.</p>
Within 3 business days	<p style="text-align: center;">Parties' Conflict of Interest Identification</p> <p>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.</p>
Within 10 business days	<p style="text-align: center;">Provider or Facility Submits Information</p> <p>The provider or facility should submit required information to the SDR entity within <i>10 business days</i> 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.</p>
Within 30 business days	<p style="text-align: center;">Patient-Provider Negotiation</p> <p>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 <i>3 business days</i> after the date of the agreement.</p>
	<p style="text-align: center;">Payment Determination by the SDR Entity</p> <p>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.</p>

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:
 - The date the item or service was provided; and
 - 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:
 - Name;
 - Email address;
 - Phone number; and
 - 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:
 - Name;

- Phone number;
- Mailing Address;
- Email;
- 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:
 - The SDR entity's name assigned to the case;
 - Mailing address;
 - Phone number; and
 - 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;
 - Ceasing collection efforts if the bill has already moved into collection;
 - 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
 - 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:
 - Do not have a financial interest in this case and are not an employee of the health care provider, facility, or patient;
 - 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 [Federal IDR portal](#) 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:

- 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), 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:
 - 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 ACASecurityandPrivacy@cms.hhs.gov 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:
 - 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.
- (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:

- 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
- 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 [45 CFR 149.160](#), provided by the provider or facility to the uninsured (or self-pay) individual;
- 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
Within 120 calendar days	<p style="text-align: center;">Before the Patient-Provider Dispute Resolution (PPDR) Process:</p> <p>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).</p> <p>The initiation notice must be sent within <i>120 calendar days</i> from when the uninsured or (self-pay) individual received their initial bill for items and services from their provider or facility.</p> <p>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.</p>
Within 3 business days	<p>2. SDR Entity Conflict of Interest Identification: 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 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 <i>3 business days</i> following selection by HHS. HHS will then assign the case to the identified alternative SDR entity to conduct the PPDR process.</p>
Within 21 calendar days	<p>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:</p> <ul style="list-style-type: none"> - 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 <p>If additional information is required, the patient has <i>21 calendar days</i> to furnish it after being notified of the information deficiency.</p>
PPDR Process:	
	<p>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.</p>
Within 3 business days	<p>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.</p>

TIMELINE	PROCESS STEP Before the Patient-Provider Dispute Resolution (PPDR) Process:
Within 10 business days	<p>6. Provider or Facility Submits Information: The provider or facility should submit any required information to the SDR entity within <i>10 business days</i> of receipt of the selection notice. This information includes:</p> <ul style="list-style-type: none"> - 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 days	<p>7. Patient-Provider Negotiation: If the parties to a PPDR 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 <i>3 business days</i> after the date of the agreement.</p> <p>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.</p>
Within 30 business days	<p>8. Payment Determination for PPDR by the SDR Entity: No later than <i>30 business days</i> 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.</p> <p>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.</p>
Time Period Extensions	<p>Extenuating Circumstances: The parties may request extensions to most of the time periods above in cases of extenuating circumstances.</p>

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](#)
- [Calendar Year 2022 Fee Guidance for the Federal Patient-Provider Dispute Resolution \(PPDR\) Process Established in Surprise Billing, Part II; Interim Final Rule with Comment Period](#)

This communication was printed, published, or produced and disseminated at U.S. taxpayer expense. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.