

Supporting Statement—Part A
Patient Provider Dispute Resolution Requirements Related to Surprise Billing; Part II
CMS-10853/OMB control number: 0938-NEW

A. Background

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was signed into law. The No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently.

The Act adds a new Part E of title XXVII of the Public Health Service Act establishing requirements applicable to providers, and facilities. These include provisions at new PHS Act sections 2799B-6 which requires providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service for an individual. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, a Federal Employees Health Benefits (FEHB) plan,¹ or a Federal health care program and if enrolled in a group health plan, or group or individual health insurance coverage, or a health benefits plan under chapter 89 of title 5,² whether the individual is seeking to have a claim for such item or service submitted to such plan or coverage (hereafter referred to as an “uninsured (or self-pay) individual”). In the case that an uninsured (or self-pay) individual requesting a good faith estimate for an item or service or schedules an item or service to be furnished, PHS Act section 2799B-6(2)(B) and the October 2021 interim final rules at 45 CFR 149.610³ require providers and facilities to furnish the good faith estimate to the uninsured (or self-pay) individual.

No Surprises Act Section 112 also adds PHS Act section 2799B-7 as added by the interim final rules at 45 CFR 149.620⁴ which directs the Secretary of HHS to establish a process under which an uninsured (or self-pay) individual can avail themselves of a patient-provider dispute resolution (PPDR) process if their billed charges after receiving an item or service are substantially in excess of the expected charges listed in the good faith estimate furnished by the provider or facility, pursuant to PHS Act section 2799B-6.

¹ HHS interprets the requirements described in PHS Act section 2799B-6 to apply with respect to FEHB covered individuals as they would to other individuals enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer. Although PHS Act section 2799B-6 does not reference health benefits plans under chapter 89 of title 5, the definition of “uninsured individual” at PHS Act section 2799B-7 does include individuals who do not have benefits under these health benefits plans, and these sections work together to provide protections for the uninsured (or self-pay) population. Moreover, the requirement for the provision of an advance explanation of benefits required by PHS Act section 2799A-(1)(f), ERISA section 716(f), and Code section 9816(f) and 5 U.S.C. 8902(p) cannot be accomplished by a FEHB carrier unless it receives a good faith estimate from a provider in accordance with PHS Act section 2799B-6(2)(A).

² A health benefits plan offered under chapter 89 of title 5, United States Code is also known as a Federal Employees Health Benefits (FEHB) plan.

³ <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-149/subpart-G/section-149.610>

⁴ <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-149/subpart-G/section-149.620>

This information collection request (ICR) focuses on the patient-provider dispute resolution process requirements under the October 2021 interim final rules (October 7, 2021, 86 FR 55980). Based on the legislative and regulatory authority outlined above, the requirements are summarized as follows:

- A patient-provider dispute resolution process for uninsured (or self-pay) individuals who receive a final bill from a provider or facility that is substantially in excess of the furnished good faith estimate. (45 CFR 149.620)
 - See Appendix 1. Selected Dispute Resolution (SDR) Entity Declining Eligibility or Need More Information Notice; Appendix 2. PPDR Dispute Initiation Form; Appendix 3. SDR Entity Certification Data Elements; Appendix 4. HHS Vendor Management (VM) Data Elements; Appendix 5. PPDR Data Elements for Patients and Providers; Appendix 6. SDR Entity Determination Notice; Appendix 7. SDR Entity Selection Notice; Appendix 8. PPDR Payment Settlement Form; Appendix 9. SDR Entity Confirmation of Receipt of Settlement Information; Appendix 10. Request for Extension

B. Justification

1. Need and Legal Basis

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was signed into law. The No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently.

The No Surprises Act also includes provisions that require health care providers and health care facilities to furnish good faith estimates upon request or upon scheduling items or services to uninsured (or self-pay) individuals. In order to implement these good faith estimate provisions under PHS Act section 2799B-6(1) and 2799B-6(2)(B), as added by section 112 of the No Surprises Act, HHS is adding 45 CFR 149.610 to establish requirements for providers and facilities to specifically inquire about an individual's health coverage status and establish requirements for providing a good faith estimate to uninsured (or self-pay) individuals.

PHS Act section 2799B-6(2) and the October 2021 interim final rules specify that a provider or facility must provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such items or services (including any items or services that are reasonably expected to be provided in conjunction with such scheduled items or services and such items or services reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes (i.e., ICD, CPT, HCPCS, DRG, and/or NDC codes) for any such items or services. The definitions related to good faith estimates of expected charges for uninsured (or self-pay) individuals for scheduled items and services and upon request, requirements for the providers and facilities, timing, and good faith estimate content requirements are set forth in PHS Act section 2799B-6 and implementing regulation at 45 CFR 149.610, established under the October 2021 interim final rules.

PHS Act section 2799B-7, as added by section 112 of the No Surprises Act, provides further protections for uninsured (or self-pay) individuals by requiring the Secretary of HHS to establish a process (in this section referred to as patient-provider dispute resolution) under which an uninsured (or

self-pay) individual who received from a provider or facility, a good faith estimate of the expected charges, and who, after being furnished the item or service, is billed for charges that are substantially in excess of the estimate, may seek a determination from an SDR entity of the amount of charges to be paid. HHS is adding new 45 CFR 149.620 to implement the patient-provider dispute resolution process including specific definitions related to the patient-provider dispute resolution process. HHS is also codifying provisions related to: eligibility for the federal patient-provider dispute resolution process; selection of an SDR entity; fees associated with this section; certification of SDR entities; and deferral to state patient-provider dispute resolution processes.

The information collections in the October 2021 interim final rules the advance the legislative goals of the No Surprises Act.

2. Information Users

HHS will request information from uninsured (or self-pay) individuals in order to initiate patient-provider dispute resolution process. This information will be used to help determine eligibility for the patient-provider dispute resolution process and is necessary for determining which provider or facility should be contacted for dispute resolution. Providers and facilities are required to submit information to SDR entities to inform the SDR entity's payment determinations.

3. Use of Information Technology

HHS does not restrict the use of electronic technology to process all information collected by HHS. For the patient-provider dispute resolution process, including the selection of the SDR entity, the process will be administered through the same HHS-owned portal system. In the case of the patient-provider dispute resolution initiation notification, the individual may request dispute resolution through the HHS-owned portal, electronically, or on paper.

4. Duplication of Efforts

There is no duplication of efforts for the information collection requirements.

5. Burden on Small Businesses

Providers and facilities incurring burden related to these requirements include providers of air ambulance services, rural health centers, federally qualified health centers, laboratories, and imaging centers, many of which may be small businesses. The Departments have tried to minimize the burden on all respondents.

6. Less Frequent Collection

This information collection is required to fulfill the statutory requirements in the CAA. Uninsured (or self-pay) individuals will not be able to obtain a good faith estimate, nor will they be able to initiate the patient-provider dispute resolution process, if this collection is conducted less frequently.

Additionally, if this collection is not conducted SDR entities will not be able to submit the required materials and obtain the required certification.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A 60-day notice will publish in the Federal Register on _____. No outside consultation was sought.

9. Payments/Gifts to Respondents

There is no payment/gift to respondents.

10. Confidentiality

All information collected under this initiative will be maintained in strict accordance with statutes and regulations governing confidentiality requirements.

11. Sensitive Questions

There are no sensitive questions associated with these information collections.

12. Burden Estimates (Hours & Wages)

To derive average costs, we are using data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). In this regard, the Table 1 below presents BLS' mean hourly wage, our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

Table 1. Wage Estimates

| Occupation Title | Occupational Code | Hourly Total Compensation (\$/hr) | Fringe Benefits and Overhead Cost (\$/hr) | Total Hourly Labor Costs (\$/hr) |
|---|-------------------|-----------------------------------|---|----------------------------------|
| Secretaries and Administrative Assistants, Except Legal, Medical, and Executive | 43-6014 | \$32.15 | \$32.15 | \$64.30 |
| Lawyer | 23-1011 | \$71.17 | \$71.17 | \$142.34 |
| General and Operations Manager | 11-1021 | \$55.41 | \$55.41 | \$110.82 |
| All occupations | 00-0000 | \$28.01 | \$28.01 | \$56.02 |

Collection of Information Requirements and Associated Burden Estimates

Patient-Provider Dispute Resolution Process (45 CFR 149.620)

The October 2021 interim final rules enable uninsured (or self-pay) individuals to initiate a patient-provider dispute resolution process if their final billed charges are at least \$400 more than the expected charges in the good faith estimate supplied by the provider or facility. HHS does not have data on how many claims will likely result in patient-provider dispute resolution. For the estimates in this section, HHS relied on the experience of New York State. In 2015-2018 New York state had 1,486 disputes involving surprise bills submitted to IDR, 31% of these disputes (457 in all) were found ineligible for IDR for various reasons including 8% (approximately 36 cases) due to being enrolled with self-insured plans.⁵ For purposes of this analysis, HHS assumes that going forward, New York State will continue to see 40 IDRs each year involving surprise bills for individuals enrolled with self-insured plans. Accordingly, the Departments estimate that there will be 26,659 claims that result in patient-provider dispute resolution each year.⁶

HHS estimates that it will take an average of two hours for an uninsured (or self-pay) individual or, if they use an authorized representative, one hour for their authorized representative to write, prepare,

⁵ See https://www.dfs.ny.gov/system/files/documents/2019/09/dfs_oon_idr.pdf

⁶ The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually x 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured individuals will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS assumes that 10% of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is at least \$400 greater than the total amount received in the good faith estimate, therefore 3,332,326 x 10% = 333,233. HHS assumes that 8% will engage the provider-patient dispute resolution process, therefore 333,233 x 8% = 26,659.

and send the notice to initiate the patient-provider dispute resolution to the Secretary. HHS assumes that uninsured (or self-pay) individuals will self-represent in 90% of the cases, while the remaining 10% will be represented by the uninsured (or self-pay) individual's authorized representative, as allowed by these interim final rules.

HHS assumes the authorized representative will be a lawyer. Additionally, HHS assumes that a small percentage of uninsured (or self-pay) individuals or their authorized representatives will be asked to resubmit or send additional materials to complete the initiation process. This results in an annual equivalent cost estimate of \$3,355,369.⁷ The patient-provider dispute resolution initiation notice must be submitted to the Secretary of HHS within 120 calendar days of receiving billed charges substantially in excess of the good faith estimate. This also includes an extenuating circumstance request when the uninsured (or self-pay) individual fails to initiate a patient provider dispute resolution within 120 calendar days. HHS assumes for uninsured (or self-pay) individuals that 8,973 (34 percent) of initiation notices, including those that need to be resubmitted with additional materials, will be sent electronically and 17,419 (66 percent) of the initiation notices, including those that need to be resubmitted with additional materials, will be mailed with an associated printing and materials and postage costs of \$13,587.^{8,9}

To facilitate communication between parties and compliance with this notice requirement, HHS is concurrently issuing a model notice that the parties may use to satisfy the patient-provider dispute resolution initiation notice requirement. HHS will consider timely use of the model notice in accordance with the accompanying instructions to satisfy the notice requirement.

These interim final rules require the SDR entity to attest to the Secretary of HHS whether a conflict of interest exists with the uninsured (or self-pay) individual, provider, or facility. HHS assumes that it will take an average of one hour for a general and operations manager and one hour for a lawyer to determine whether a conflict of interest exists. HHS assumes all communication will be done electronically. This results in annual equivalent cost estimate of \$6,748,992¹⁰ as shown in Table 2.

⁷ The burden is estimated as follows: $26,659 \times 90\% = 23,993$ uninsured (or self-pay) individuals will self-represent. $23,993 \times 2 \text{ hours} = 47,986$ hours. A labor rate of \$56.02 is used for uninsured (or self-pay) individuals (all occupations). The labor rate is applied in the following calculation: $23,993 \text{ claims} \times 2 \text{ hours} \times \$56.02 = \$2,688,176$. HHS assumes that uninsured (or self-pay) individual will appoint an authorized representative in 10% of cases. $26,659 \times 10\% = 2,666$ claims represented by an authorized representative. Therefore, the burden estimate is estimated as follows: $2,666 \text{ claims represented by lawyers} \times 1 \text{ hour} = 2,666$ hours. A labor rate of \$142.34 is used for a lawyer. The labor rates are applied in the following calculation: $2,666 \text{ claims} \times 1 \text{ hour} \times \$142.34 = \$379,478$. HHS assumes approximately 15% of uninsured (or self-pay) individuals (10% who self-represent + 5% who appoints an authorized representative) will need to resubmit or submit additional materials to initiate IDR, either themselves or through their authorized representative. Therefore, the burden estimate is calculated as follows: $23,993 \text{ claims} \times 10\% = 2,399$ resubmitted claims by individual $\times 2 \text{ hours} \times \56.02 (labor rate) = \$268,784. $2,666 \text{ claims} \times 5\% = 133$ resubmitted claims by authorized representative $\times 1 \text{ hour} \times \142.34 (labor rate) = \$18,931. The total annual respondent time cost estimates are added as follows: $\$2,688,176 + \$379,478 + \$268,784 + \$18,931 = \$3,355,369$. The total burden hours are 55,584.

⁸ HHS assumes that the average initiation notice sent via mail by uninsured (or self-pay) individuals will be three pages in length and printed on 8.5" x 11" sized paper. HHS assumes a \$0.05 cost in printing and materials cost per page and \$0.63 in postage cost. Therefore, $\$0.05 \text{ cost per page} \times 3 \text{ pages} \times 17,419 \text{ mailed initiation notices}$ (inclusive of notices that needed to be resubmitted) = \$2,613 in printing and material costs. The postage costs are calculated as $\$0.63 \text{ cost per postage} \times 17,419 \text{ mailed initiation notices} = \$10,974$ in postage cost. The total printing and materials and postage costs are therefore $\$2,613 + \$10,974 = \$13,587$.

⁹ According to data from the National Telecommunications and Information Agency, 34 percent of households in the United States accessed health records or health insurance online. <https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show>.

¹⁰ The burden is estimated as follows: $26,659 \text{ claims} \times 1 \text{ hour} = 26,659$ hours. A labor rate of \$110.82 is used for a general and operations manager. The labor rate is applied in the following calculation: $26,659 \text{ claims} \times 1 \text{ hour} \times \$110.82 = \$2,954,350$. The burden for legal review is estimated as follows: $26,659 \text{ claims} \times 1 \text{ hour} = 26,659$ hours. A labor rate of \$142.34 is used for a lawyer. The labor rates are applied in the following calculation: $26,659 \text{ claims}$

Table 2. Estimated Annual Cost and Hour Burden Related to SDRE Attestation of Conflict of Interest with a Patient-Provider Dispute Resolution Initiation Notice

| Requirement/ Notice | Estimated Number of Respondents | Estimated Number of Responses (per Respondent) | Total Responses (All Respondents) | Burden per Response (Hours) | Total Annual Burden (Hours) | Total Estimated Cost |
|--|---------------------------------------|--|--|-----------------------------------|--------------------------------------|----------------------------|
| SDRE Attestation of Conflict of Interest with a PPDR Initiation Notice | 26,659 | 1 | 26,659 | 2 | 53,318 | \$6,748,992 |

These interim final rules allow uninsured (or self-pay) individuals to attest to having a conflict of interest with the SDRE that is assigned to their dispute resolution request. In the event of a conflict of interest with the SDRE, uninsured (or self-pay) individuals may notify HHS to initiate further review by HHS. HHS estimates that it will take one hour for an uninsured (or self-pay) to write, prepare and send the notice to HHS. HHS estimates that approximately 66 percent of uninsured (or self-pay) individuals will send a note in the mail that is one page in length.¹¹ HHS assumes that each uninsured (or self-pay) individual will incur a printing and materials cost of \$0.05 per page and a postage cost of \$0.63 per mailing. Therefore, the annual equivalent cost estimate is \$1,504,205¹² for all uninsured (or self-pay) individuals as shown in Table 3.

Table 3. Estimated Annual Cost and Hour Burden related to Patients Attestation of Conflict of Interest with SRDE Notice

| Requirement/ Notice | Estimated Number of Respondents | Estimated Number of Responses (per Respondent) | Total Responses (All Respondents) | Burden per Response (Hours) | Total Annual Burden (Hours) | Total Estimated Cost |
|--|---------------------------------------|--|--|-----------------------------------|--------------------------------------|----------------------------|
| Patients Attestation of Conflict of Interest with SRDE Notice | 26,659 | 1 | 26,659 | 1 | 26,659 | \$1,504,205 |

HHS requires that the uninsured (or self-pay) individuals notify the SDRE if a conflict of interest is determined. To facilitate receipt and review of the notification of conflict of interest, the SDRE must in

x1 hour x \$142.34= \$3,794,642. The total annual response time cost estimates are added as follows: \$2,954,350 + \$3,794,642= \$6,748,992. The total burden hours are 53,317.

¹¹ HHS assumes that the good faith estimate will be printed in 8.5" x 11" letter sized paper.

¹² The burden is estimated as follows: 26,659 claims x 1 hour = 26,659 hours. A labor rate of \$56.02 is used for uninsured (or self-pay) individuals (all occupations). The labor rate is applied in the following calculation: 26,659 (notification letters) x 1 hour x \$56.02 = \$1,493,437. HHS assumes a \$0.05 cost in printing and materials cost per page and \$0.63 in postage cost. Therefore, the printing and material costs are calculated as \$0.05 cost per page x 1 page x 15,835 (66% of notification letters) = \$792. The postage costs are calculated as \$0.63 cost per postage x 15,835 mailed notification letters = \$9,976 in postage cost. The total printing and materials and postage costs are therefore \$792 + \$9,976 = \$10,768. The total annual respondent time cost estimates are added as follows: \$1,493,437+ \$10,768= \$1,504,205. The total burden hours are 26,659.

turn, submit the notification of conflict of interest notice to the Secretary of HHS on behalf of uninsured (or self-pay) individuals. HHS estimates that it will take a clerical worker 30 minutes to send these notices to HHS. HHS assumes that each SDRE will submit these notices to HHS via email correspondence with no associated printing and mailing costs. Therefore, the annual equivalent cost estimate is \$857,087¹³ as shown in Table 4.

Table 4. Estimated Annual Cost and Hour Burden related to SDRE Attestation of Conflict of Interest with HHS Notice (When the SDRE Submit the Notification of Conflict of Interest Notice to HHS on Behalf of Patients)

| Requirement/Notice | Estimated Number of Respondents | Estimated Number of Responses (per Respondent) | Total Responses (All Respondents) | Burden per Response (Hours) | Total Annual Burden (Hours) | Total Estimated Cost |
|--|---------------------------------|--|-----------------------------------|-----------------------------|-----------------------------|----------------------|
| SDRE Attestation of Conflict of Interest with HHS Notice (When the SDRE Submit the Notification of Conflict of Interest Notice to HHS on Behalf of Patients) | 26,659 | 1 | 26,659 | 0.5 | 13,329 | \$857,087 |

These interim final rules allow the provider to attest to having a conflict of interest with the SDRE. If a provider or facility has a conflict of interest with the SDRE, they can notify HHS and a new SDRE without a conflict of interest will be assigned to their case. HHS estimates that it will take a clerical worker 30 minutes to send the notification letters. HHS assumes that each provider or facility will receive the notification via email correspondence with no associated printing and mailing costs. Therefore, the annual equivalent cost estimate is \$857,087¹⁴ for all providers and facilities as shown in Table 5.

Table 5: Estimated Annual Cost and Hour Burden Related to Providers/ Facilities Attestation of Conflict of Interest with SRDE Notice

| Requirement/Notice | Estimated Number of Respondents | Estimated Number of Responses (per Respondent) | Total Responses (All Respondents) | Burden per Response (Hours) | Total Annual Burden (Hours) | Total Estimated Cost |
|--|---------------------------------|--|-----------------------------------|-----------------------------|-----------------------------|----------------------|
| Providers/ Facilities Attestation of Conflict of Interest with SRDE Notice | 26,659 | 1 | 26,659 | 0.5 | 13,329 | \$857,087 |

HHS requires that the provider or facility notify the HHS if a conflict of interest is determined. To facilitate receipt and review of the notification of conflict of interest, HHS estimates that it will take a

¹³ The burden is estimated as follows: 26,659 claims x 0.5 hour = 13,329 hours. A labor rate of \$64.30 is used for a clerical worker. The labor rate is applied in the following calculation: 26,659 (claims) x 0.5 hours x \$64.30 = \$857,087.

¹⁴ The burden is estimated as follows: 26,659 providers/facilities x 0.5 hour = 13,329 hours. A labor rate of \$64.30 is used for a clerical worker. The labor rate is applied in the following calculation: 26,659 (notification letters) x 0.5 hours x \$64.30 = \$857,087.

clerical worker 30 minutes to notify HHS of each conflict of interest. HHS assumes that each SDRE entity send notices to HHS via email correspondence with no associated printing and mailing costs. Therefore, the annual equivalent cost estimate is \$857,087¹⁵ as shown in Table 6.

¹⁵ The burden is estimated as follows: 26,659 claims x 0.5 hour = 13,329 hours. A labor rate of \$64.30 is used for a clerical worker. The labor rate is applied in the following calculation: 26,659 (claims) x 0.5 hours x \$64.30 = \$857,087.

Table 6. Estimated Annual Cost and Hour Burden Related to SDRE Attestation of Conflict of Interest with HHS Notice (When the SDRE Submit the Notification of Conflict of Interest Notice to HHS on Behalf of Providers/Facilities)

| Requirement/Notice | Estimated Number of Respondents | Estimated Number of Responses (per Respondent) | Total Responses (All Respondents) | Burden per Response (Hours) | Total Annual Burden (Hours) | Total Estimated Cost |
|--|---------------------------------|--|-----------------------------------|-----------------------------|-----------------------------|----------------------|
| SDRE Attestation of Conflict of Interest with HHS Notice (When the SDRE Submit the Notification of Conflict of Interest Notice to HHS on Behalf of Providers/Facilities) | 26,659 | 1 | 26,659 | 0.5 | 13,329 | \$857,087 |

HHS notifies both uninsured (or self-pay) individuals and providers or facilities about the outcome of the conflict of interest via email correspondence with no associated printing and mailing costs while requiring no further information from the parties.¹⁶

These interim final rules also require the SDR entity to review eligibility and completeness of the initiation notice and notify uninsured (or self-pay) individuals, providers or facilities of the SDR entity's selection to conduct dispute resolution. Providers and facilities are thereafter required to furnish additional information to the SDR entity within 10 business days after receiving notification of SDR entity selection. This information must include: (1) a copy of the good faith estimate provided to the uninsured (or self-pay) individual for the items or services under dispute; (2) a copy of the bill provided to the uninsured (or self-pay) individual for items or services under dispute; and (3) if available, documentation providing evidence to demonstrate the difference between the good faith estimate and the billed charge reflects 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. HHS estimates that it will take an average of one hour for a general and operations manager to address these requirements and send to the SDR entity. This results in an annual equivalent cost estimate of \$2,954,350.¹⁷

These interim final rules require the SDR entity to assess the information provided by the provider or facility according to the standards described in 45 CFR 149.620(f) and discussed in section VI.B.7 of the preamble. The SDR entity must make a determination within 30 days after receipt of information from the provider or facility. HHS estimates that it will take an average of two hours for a general and operations manager and two hours for a lawyer to assess the merits of the submitted information and determine a prevailing party. This results in an annual equivalent cost estimate of \$13,497,985¹⁸ as shown in Table 7.

¹⁶ The labor cost associated to email the notification letters is accounted for annual ongoing costs associated with implementation and the administration of the PPDR program in the federal government cost under section 14.

¹⁷ The burden is estimated as follows: 26,659 claims x 1 hour = 26,659 hours. A labor rate of \$110.82 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims x 1 hour x \$110.82 = \$2,954,350. Total burden hours are 26,659 hours.

¹⁸ The burden is estimated as follows: 26,659 claims x 2 hours = 53,317 hours. A labor rate of \$110.82 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims x 2 hours x

Table 7. Estimated Annual Burden to Assess the Submitted Information and Determine a Prevailing Party

| Requirement/Notice | Estimated Number of Respondents | Estimated Number of Responses (per Respondent) | Total Responses (All Respondents) | Burden per Response (Hours) | Total Annual Burden (Hours) | Total Estimated Cost |
|--|---------------------------------|--|-----------------------------------|-----------------------------|-----------------------------|----------------------|
| Assessment of the Submitted Information and Determine a Prevailing Party | 26,659 | 1 | 26,659 | 4 | 106,634 | \$13,497,985 |

HHS estimates that it will take an average of 30 minutes for an SDR entity's general and operations manager to notify parties of the SDR entity's determination. This results in an annual equivalent cost estimate of \$1,477,175.¹⁹

The SDR entity must also submit the administrative fee to the Secretary of HHS on behalf of disputing parties. This burden includes time to review instructions, search existing data resources, gather data needed, and complete and review the information collection. HHS estimates that the time required to complete and submit this information collection is estimated to average a clerical worker 1.5 hours per month (or 18 hours annually), with a total annual cost of \$3,472²⁰, as shown in Table 8.

Table 8. Estimated Annual Burden and Cost Related to SDR Entity Submission of the Administrative fee to HHS

| Requirement/Notice | Estimated Number of Respondents | Total Annual Burden (1.5 hours x 12 months) | Annual Cost Per IDR entity | Annual Cost for all Responses |
|--|---------------------------------|---|----------------------------|-------------------------------|
| SDRE Submission of the Administrative Fee to HHS | 3 | 18 | 1,157 | \$3,472 |

The total annual burden associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals and providers and facilities is 322,189 hours with an equivalent cost of \$32,112,809 as shown in Table 9 below. HHS invites comments on the assumptions and calculations made in these ICRs.

\$110.82 = \$5,908,701. The burden for legal review is estimated as follows: 26,659 claims x 2 hours = 53,317 hours. A labor rate of \$142.34 is used for a lawyer. The labor rates are applied in the following calculation: 53,317 x \$142.34 = \$7,589,284. The total annual respond time cost estimates are calculated as follows: \$5,908,701 + \$7,589,284 = \$13,497,985. The total annual burden hours are 106,634 hours.

¹⁹ The burden is estimated as follows: 26,659 claims x 0.5 hour = 13,330 hours. A labor rate of \$110.82 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims x 0.5 hour x \$110.82 = \$1,477,175. Total burden hours are 13,330 hours.

²⁰ The burden is estimated as follows: A labor rate of \$64.30 is used for a clerical worker. The labor rate is applied in the following calculation: 3 annual responses x 18 hours x \$64.30 = \$3,472.

Table 9: Summary of Annual Burden Estimates

| Requirement/Notice | Estimated Number of Respondents | Estimated Number of Responses (per Respondent) | Total Responses (All Respondents) | Burden per Response (Hours) | Total Annual Burden (Hours) | Total Estimated Cost |
|--|---------------------------------|--|-----------------------------------|-----------------------------|-----------------------------|----------------------|
| Uninsured or Self-Pay Individuals and Authorized Representatives to Write, Prepare and Send the Initiation Notice for the PPDR to HHS, including Resubmission Costs Notice | 26,659 | 1.15 | 30,658 | 1.8 | 55,584 | \$3,355,369 |
| SDRE Attestation of Conflict of Interest with a PPDR Initiation Notice | 26,659 | 1 | 26,659 | 2 | 53,318 | \$6,748,992 |
| Patients Attestation of Conflict of Interest with SRDE Notice | 26,659 | 1 | 26,659 | 1 | 26,659 | \$1,504,205 |
| SDRE Attestation of Conflict of Interest with HHS Notice (When the SDRE Submit the Notification of Conflict of Interest Notice to HHS on Behalf of Patients) | 26,659 | 1 | 26,659 | 0.5 | 13,329 | \$857,087 |
| Providers/ Facilities Attestation of Conflict of Interest with SRDE Notice | 26,659 | 1 | 26,659 | 0.5 | 13,329 | \$857,087 |
| SDRE Attestation of Conflict of Interest with HHS Notice (When the SDRE Submit the Notification of Conflict of Interest Notice to HHS on Behalf of Providers/Facilities) | 26,659 | 1 | 26,659 | 0.5 | 13,329 | \$857,087 |
| Uninsured or Self-Pay Individuals and Providers or Facilities to Furnish Additional Information to Selected SDR Entities Notice | 26,659 | 1 | 26,659 | 1 | 26,659 | \$2,954,350 |

| | | | | | | |
|---|--------|---|--------|-----|---------|--------------|
| Assessment of the Submitted Information and Determine a Prevailing Party Notice | 26,659 | 1 | 26,659 | 4 | 106,634 | \$13,497,985 |
| SDRE Notification to the Parties of the SDRE's Determination Notice | 26,659 | 1 | 26,659 | 0.5 | 13,330 | \$1,477,175 |
| SDRE Submission of the Administrative fee to HHS | 3 | | 3 | 6 | 18 | \$3,472 |
| Total | | | | | 322,189 | \$32,112,809 |

Information Collection Instruments and Instruction/Guidance Documents

Appendix 1: Ineligible for Patient-Provider Dispute Resolution or Additional Information Needed

Appendix 2: Patient-Provider Dispute Resolution Form

Appendix 3: Patient-Provider Selected Dispute Resolution (SDR) Entity Certification Application Data Elements

Appendix 4: Independent Dispute Resolution and Patient-Provider Dispute Resolution Processes; Vendor Management Data Elements

Appendix 5: Patient-Provider Dispute Resolution Process Data Elements

Appendix 6: Selected Dispute Resolution (SDR) Determination Notice to Parties Provided Under the No Surprises Act

Appendix 7: Selected Dispute Resolution (SDR) Entity Notification to Health Care Providers and Facilities and Uninsured (or Self-Pay) Individuals

Appendix 8: Uninsured (or Self-Pay) Individual and Provider or Facility Settle on a Payment Amount After Initiating Patient- Provider Dispute Resolution

Appendix 9: Selected Dispute Resolution (SDR) Entity Notification to Health Care Provider or Facility and Uninsured (or Self-Pay) Individual Confirming Receipt of Dispute Settlement and Action

Appendix 10: Standard Notice: Uninsured (or Self-Pay) Individual, Provider or Facility's Notification to Secretary of Health and Human Services Requesting Extension

13. Capital Costs

HHS estimates the overall printing, materials and mailing costs for uninsured (or self-pay) individuals to send initiation notices for dispute resolution to the Secretary of HHS (\$13,587) and to attest

conflict of interest with SRDE notice (\$11,086) is estimated to be \$24,673.²¹

14. Cost to Federal Government

HHS estimates the total annual ongoing costs associated with implementation and the administration of the PPDR program, including system maintenance, and program support, is estimated to be \$12.6 million, this cost will be offset by the collection of the \$25 administrative fee, resulting in a total anticipated collection of \$666,475 and a total approximate annual cost to the federal government of \$12 million.

15. Changes to Burden

This is a new information collection request.

16. Publication/Tabulation Dates

There are no plans to publish the outcome of the information collection.

17. Expiration Date

The expiration date will be displayed on the first page of each instrument (top, right-hand corner).

²¹ HHS assumes that notices will be printed in 8.5" x 11" letter sized paper, \$0.05 cost in printing and materials cost per page and \$0.63 in postage cost.