Supporting Statement—Part A
Requirements Related to Surprise Billing; Part II
CMS-10791/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 CAA added provisions applicable to group health plans and health insurance issuers in the group and individual markets in a new Part D of title XXVII of the Public Health Service Act (PHS Act), and added new provisions to Employee Retirement Income Security Act (ERISA) Part 7, and Subchapter B of chapter 100 of the Internal Revenue Code (Code). Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A-1, which contain limitations on cost sharing and requirements for initial payments for emergency services. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A-1 to establish a federal independent dispute resolution (federal IDR) process that allows plans and issuers and out-of-network providers to resolve disputes regarding out-of-network rates. Section 105 of the No Surprises Act created Code section 9817, ERISA section 717, and PHS Act section 2799A-2 which contain limitations on cost sharing and requirements for initial payments for air ambulance services, and allow plans and issuers and providers of air ambulance services to access the federal IDR process. CAA provisions that apply to health care providers and facilities, and providers of air ambulance services, such as requirements around cost sharing, prohibitions on balance billing for certain items and services, and requirements related to disclosures about balance billing protections, were added to title XXVII of the PHS Act in a new part E.

The No Surprises Act also amended the Federal Employees Health Benefits (FEHB) Act, 5 U.S.C. 8901 *et seq.,* by adding a new subsection (p) to 5 U.S.C. 8902. Under this new provision, each FEHB Program contract must require a carrier to comply with provisions of sections 9816 and 9817 of the Code; sections 716 and 717 of ERISA; and sections 2799A–1 and 2799A–2 of the PHS Act (as applicable) in the same manner as they apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage. Likewise, the provisions of sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act apply to health care providers, facilities, and providers of air ambulance services with respect to covered individuals in FEHB plans in the same manner as they apply to participants, beneficiaries, or enrollees in group health plans or coverage offered by health insurance issuers.

Additionally, the No Surprises 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

[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

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 September interim final rules at 45 CFR 149.610 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 these interim final rules at 45 CFR 149.620, 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. Under PHS Act section 2799B-7, an uninsured (or self-pay) individual means, with respect to an item or service, an individual who does not have benefits for such 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, but does not seek to have a claim for such item or service submitted to such plan or coverage).

This Paperwork Reduction Act (PRA) submission focuses on information collection requirements (ICRs) related to HHS requirements under the September 2021 interim final rules. Based on the legislative and regulatory authority outlined above, the ICRs are summarized as follows:

- Health care provider and facility requirements to inform uninsured (or self-pay) individuals both verbally and in writing of the availability of a good faith estimate of expected charges. (45 CFR 149.610)
    - See Appendix 1. Right to Receive a Good Faith Estimate of Expected Charges Notice. Health care provider and facility requirements to furnish good faith estimates to individuals who are not enrolled in a plan or coverage or a federal health care program, or not seeking to file a claim with their plan or coverage (uninsured or self-pay individuals) when scheduling an item or service, or upon request. (45 CFR 149.610); Appendix 2. Good Faith Estimate Template; Appendix 11. Good Faith Estimate Data Elements. Please note: consumers are not being asked to sign Good Faith Estimate forms as listed in Appendices 1 and 2 as these are not consent forms but for informational purposes and for the purposes of initiating the Patient-Provider Dispute Resolution process, if necessary.
- 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 than the furnished good faith estimate. (45 CFR 149.620)

---

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.

- See Appendix 3. Selected Dispute Resolution (SDR) Entity Declining Eligibility or Need More Information Notice; Appendix 4. Dispute Initiation Form; Appendix 5. SDR Entity Certification Data Elements; Appendix 6. Vendor Management Data Elements; Appendix 7. PPDR Data Elements for Patients and Providers; Appendix 8. SDR Entity Determination Notice; Appendix 9. SDR Entity Selection Notice; Appendix 10. PPDR - Payment Settlement Form

The Departments will be requesting approval of the emergency review requests by the effective date of these September 2021 interim final rules. The Departments will be seeking approval for the ICR for 180 days, the maximum allowed for an ICR approved using an emergency review. As part of the emergency review request, the Departments will be requesting that OMB waive the notice requirement set forth in 5 CFR 1320.13(d). Once the emergency submission is approved, the Departments will initiate an ICR Revision, the process required under the PRA to seek up to three (3) years of approval for the information collections. As part of the process, the Departments will open a 60-day and 30-day comment period on the ICR.

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 September 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 September 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 ICRs in the September 2021 interim final rules advance the legislative goals of the No Surprises Act.

HHS has submitted requests for new ICRs containing the information collection requirements for good faith estimates and the patient-provider dispute resolution process created by the No Surprises Act to be processed as an Emergency Clearance Request in accordance with section 5 CFR 1320.13 of the Paperwork Reduction Act, Emergency Processing. The Emergency processing request under the PRA is being requested on the same basis that good cause was found by the Departments and the OPM Director to issue the IFR. The Departments and OPM Director have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until after a full public notice and comment process has been completed. Although this effective date may have allowed for the regulations, if promulgated with the full notice and comment rulemaking process, to be applicable in time for the applicability date of the provisions in the No Surprises Act, this timeframe would not provide sufficient time for the regulated entities to implement the requirements.

2 Information Users

The information requirements of the interim final rules have two components regarding good faith estimates and patient-provider dispute resolution for uninsured (or self-pay) individuals.

Good Faith Estimates. Providers and facilities must furnish a good faith estimate of expected items and services beginning on or after January 1, 2022 which will allow uninsured (or self-pay) individuals to have access to information about health care pricing before receiving care. This information will allow uninsured (or self-pay) individuals to evaluate options for receiving health care, make cost-conscious health care purchasing decisions, and reduce surprises in relation to their health care costs for items and services. Additionally, uninsured (or self-pay) individuals will need a good faith estimate to initiate the patient-provider dispute resolution process.

Patient-Provider Dispute Resolution Process. 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 determination decisions.

3 Use of Information Technology

HHS assumes that all information collected by HHS will be sent electronically. Specifically:

- The notice on the availability of a good-faith estimate will be posted on providers' and facilities' websites;

- Convening providers and facilities are required to provide the good faith estimate to the uninsured (or self-pay) individual either by paper or electronically, pursuant to the uninsured (or self-pay) individual's requested format, and in the latter case, technology must be used; and
- 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 an electronic notice sent through the portal.

4 Duplication of Efforts

There is no duplication of efforts for these ICRs.

5 Burden on Small Businesses

Providers and facilities incurring burden related to these ICRs 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 collection of information 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 information collection is conducted less frequently. Additionally, if this information 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

An interim final rule with requests for comments will publish on September 30, 2021. HHS has submitted a request for a new ICR containing the information collection requirements for good faith estimates and the patient-provider dispute resolution process created by the No Surprises Act be processed as an Emergency Clearance Request in accordance with section 5 CFR 1320.13 of the Paperwork Reduction Act, Emergency Processing. The Emergency processing request under the PRA is being requested on the same basis that good cause was found by the Departments and the OPM Director to issue these interim final rules. The Departments and OPM Director have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until after a full public notice and comment process has been completed. Although this effective date may have allowed for the regulations, if promulgated with the full notice and comment rulemaking process, to be applicable in time for the applicability date of the provisions in the No Surprises Act, this timeframe would not provide sufficient time for the regulated entities to implement the requirements.

The Departments have also conducted stakeholder meetings and received letters from stakeholders to obtain their reviews regarding this IFR.

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 ICRs.

12 Burden Estimates (Hours & Wages)

To derive wage estimates, we generally used data from the Bureau of Labor Statistics[3] to derive average labor costs for estimating the burden associated with the ICRs. The methodology for calculating the hourly compensation, overhead cost, and total hourly labor cost for occupations is based on DOL methodology.[4] Table 1 below presents the hourly compensation, overhead cost, and total hourly labor cost for occupations.

Table 1. Total Costs by Occupation

Occupation Title	Occupational Code	Hourly Total Compensation ($/hr)	Overhead Cost ($/hr.)	Total Hourly Labor Costs ($/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43-6014	$28.96	$26.27	$55.23
Lawyer	23-1011	$105.28	$35.68	$140.96
Computer Programmers	15-1251	$67.62	$46.15	$113.77
Medical Secretaries and Administrative Assistants	43-6013	$27.94	$18.13	$46.07
Human Resources Specialists	13-1071	$49.09	$42.74	$91.83

[3] May 2020 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at https://www.bls.gov/oes/current/oes_stru.htm.

[4] https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf

Business Operations Specialist	13-1198	$59.60	$41.72	$101.32
General and Operations Manager	11-1021	$88.25	$34.30	$122.55
Compensation and Benefits Manager	Nov-11	$96.97	$24.81	$121.78
Computer and Information Systems Managers	Nov-21	$113.52	$53.38	$155.52
Computer and Information Systems Managers	11-3021	$113.52	$53.38	$166.90
Medical and Health Services Manager	11-9110	$83.39	$21.62	$105.01
Physician (all other)	29-1228	$154.74	$14.66	$169.40
All occupations	00-0000	$39.40	$ 24.92	$64.32

12.1 ICRs Regarding Notice of Right to Good Faith Estimates for Uninsured (or Self-Pay) Individuals (45 CFR 149.610)

Convening providers and facilities are required under 45 CFR 149.610(b) to inform uninsured (or self-pay) individuals of the availability of good faith estimates of expected charges. The notice regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by individual(s) seeking items and services with such convening provider or convening facility. Additionally, the notice must be prominently displayed (and easily searchable from a public search engine), on the convening provider's or convening facility's website, in the convening provider's or convening facility's office, and on-site where scheduling or questions about the cost of items and services occur. These ICRs estimate the information collection burdens for three groups of provider types: (1) providers associated with health care facilities, (2) individual physician practitioners, and (3) wholly physician-owned private practices. For all three groups of providers, the ICRs apply the same methodology to estimate the burden, consisting of the following steps:

- Drafting notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges.
- Displaying the notices on the provider's website, in the provider's office, and on-site where scheduling or questions about the cost of items or services occur.
- Posting a single page notice in at least two prominent locations.
- Printing and materials costs for posting notices.

Details about the requirements of the steps that apply to all three provider groups are described once for providers associated with health care facilities and apply equally to the other two provider groups. Any specific differences in estimating the burden to comply with these requirements are detailed

for the specific provider group below. HHS invites comment on the assumptions and calculations made in these ICRs.

Providers Associated with Health Care Facilities

Unique to providers associated with health care facilities, HHS assumes that such providers will enter into agreements with their associated health care facility to provide notice of the availability of good faith estimates of expected charges to uninsured (or self-pay) individuals on their behalf. HHS estimates that it will take an average of two hours for a lawyer to draft an agreement and a medical secretary and administrative assistant two hours to provide electronic copies to all associated convening providers to sign. As shown in Table 2, this results in an equivalent cost estimate of approximately $91,770,384 to be incurred as one-time cost in 2021.[5] HHS cannot estimate how many providers will incur burden to sign the agreement, but assumes the burden to providers will be minimal; the use of electronic signature portals may reduce the burden to the convening provider. In future years, this agreement can be included in the contract between the facilities and providers at no additional cost.

TABLE 2: Estimated One-Time and Hour Burden for Providers Associated with Facilities to Enter into Agreements to Provide Notice of Right to a Good Faith Estimate

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Burden (Hours)	Total Estimated Cost*
2021	245,336	245,336	4	981,344	$91,770,384

*The 6-month amount is also calculated to be $91,770,384 for purposes of this emergency PRA package. The cost does not change whether calculated over a twelve or six month timeframe.

HHS assumes that the associated facility will draft the notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by individual(s) seeking items and services with such convening provider. Additionally, the notices must be prominently displayed on the convening provider's website, and in the convening provider's office, and on-site where scheduling or questions about the cost of items or services occur. Providers may satisfy this requirement by utilizing the language in the standard notice anticipated to be issued by the Department. HHS estimates that for each health care facility, it will take an average of two hours for a lawyer to read and understand the anticipated notice and draft any additions in clear and understandable language, a medical secretary and administrative assistant 30 minutes to prepare the document for posting

[5] The burden is estimated as follows: 245,336 health care facilities x 2 hours = 490,672 hours. A labor rate of $140.96 is used for a lawyer. The labor rate is applied in the following calculation: 245,336 health care facilities x 2 hours x $140.96 = $69,165,125. 245,336 health care facilities x 2 hours = 490,672 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 245,336 health care facilities x 2 hours x $46.07 = $22,605,259. Therefore, 490,672 hours + 490,672 hours = 981,344 total burden hours and $69,165,125 + $22,605,259 = $91,770,384 total annual respondent time cost.

within the facility, and a computer programmer one hour to post the information in the provider's website on behalf of the facility. As shown in Table 3, this results in an equivalent cost of approximately $102,754,069 to be incurred as a one-time cost in 2021.[6]

TABLE 3: Estimated One-Time and Hour Burden for Health Care Facilities (Including on Behalf of Health Care Providers Associated with Health Care Facilities) to Draft and Post Notice of Good Faith Estimate

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Burden (Hours)	Printing and Materials Costs	Total Estimated Cost*
2021	245,336	245,336	2.5	858,676	$25,752	$102,754,069

*The 6-month amount is also calculated to be $102,754,069 for purposes of this emergency PRA package. The cost does not change whether calculated over a twelve or six month timeframe.

HHS assumes that each health care facility will post a single page document in at least two prominent locations so uninsured (or self-pay) individuals are provided reasonable notice of their right to a good faith estimate of expected charges. A prominent location in the health care facility may include patient appointment check-in kiosks, reception front-desks, patient appointment scheduling locations, and where patients pay bills. The notices should be drafted in clear and understandable language, shorter in length, and printed in legible font size. HHS assumes that each facility will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Hospitals may have a greater number of posting locations because of building size, therefore, HHS anticipates that hospitals will post four additional notices on average and incur an additional cost of $0.20 each. This results in a one-time equivalent cost of approximately $24,534 to all non-hospital health care facilities and an overall one-time cost of approximately $25,752 when including hospitals.

HHS estimates that the one-time burden for providers and facilities to enter into agreements and for facilities to develop, prepare, print, and post the notices and update their respective websites will be approximately 1,840,020 total burden hours with an associated equivalent cost of approximately $194,524,453 as shown in Table 4.

[6] The burden is estimated as follows: 245,336 health care facilities x 2 hours = 490,672 hours. A labor rate of $140.96 is used for a lawyer. The labor rate is applied in the following calculation: 245,336 health care facilities x 2 hours x $140.96 = $69,165,125. 245,336 health care facilities x 0.5 hours = 122,668 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 245,336 health care facilities x 0.5 hours x $46.07 = $5,651,315. 245,336 health care facilities x 1 hours = 245,336 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 245,336 health care facilities x 1 hour x $113.77= $27,911,877. Therefore, 490,672 hours + 122,668 hours + 245,336 hours = 858,676 total burden hours. Additionally, one-time printing and material costs are estimated using the following calculation: .05 x 2 pages x 245,336 impacted health care facilities = 25, 752 total one-time cost for printing and materials. The total respondent time costs are $69,165,125 + $5,651,315 + $27,911,877 + $25,752 = $102,754,069.

*TABLE 4: Total Estimated One-Time Cost and Hour Burden for Health Care Facilities (Including on Behalf of Health Care Providers Associated with Health Care Facilities) to Provide Notice of Right to a Good Faith Estimate **

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Printing and Materials Costs	Total Estimated Cost**
2021	245,336	245,336	7.5	1,840,020	$25,752	$194,524,453

*Estimated cost includes the sum of Table 30 and Table 31. It also includes computer programming cost to update health care facility website with right of good faith estimate notice to uninsured (or self-pay) individuals. Total printing and material costs of $24,534 to all non-hospital health care facilities and an overall one-time cost of approximately $25,752 when including hospitals.

**The 6-month amount is also calculated to be $194,524,453 for purposes of this emergency PRA package. The cost does not change whether calculated over a twelve or six month timeframe.

Individual Physician Practitioners

HHS estimates that 145,887 individual physician practitioners will incur burden and cost to comply with this provision.[7] HHS estimates an average of two hours and thirty minutes for the individual physician practitioner to read and understand the provided notice and draft any additions in clear and understandable language and (for 80% of individual physician practitioners) a computer programmer one hour to post the information in the provider's website. HHS estimates that the one-time burden for individual physician practitioners to develop, prepare, print, post the notices, and make website updates will be approximately 481,426 total burden hours. This results in an equivalent cost of approximately $75,075,712.[8]

[7] In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf; Professionally Active Physicians. KFF. Published May 20, 2020. https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22.

[8] The burden is estimated as follows: 145,887 individual physician practitioners x 2.5 hours = 364,717 hours. A labor rate of $169.40 is used for a physician. The labor rate is applied to the following calculation: 145,887 individual physician practitioners x 2.5 hours x $169.40 = $61,783,085. HHS assumes that 80 percent of individual physician practitioners have a website resulting in 116,709 websites needed to be updated with good faith estimate notices. HHS assumes that the physician will pay a computer programmer to make the website update. The burden is estimated as follows: 116,709 websites needing updates x 1 hour = 116,709 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 116,709 websites needing updates x 1 hour x $113.77 = $13,278,038. Therefore, 364,717 hours + 116,709 hours = 481,426 total burden hours. The total annual respondent time cost is $61,783,085 + $13,276,038 = $75,061,124. Total printing and material costs are of $14,589. Therefore, $75,061,124 + $14,589 =$75,075,712.[9] In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf; Professionally Active Physicians. KFF. Published May 20, 2020. https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22.

HHS assumes that each individual physician practitioner will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. This results in an annual one-time equivalent cost of approximately $14,589 to all individual physician practitioners.

HHS estimates that the annual one-time burden for individual physician practitioners to develop, prepare, print, post the notices, and make website updates will be approximately 481,426 total burden hours with an associated equivalent cost of approximately $75,075,712, as shown in Table 5.

*TABLE 5: Estimated One-Time Cost and Hour Burden for Individual Physician Practitioners to Draft and Post Notice of Good Faith Estimate Notice**

Year	Estimated Number of Respondents (Occupation Type)	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Printing and Material Costs	Total Estimated Cost**
2021	145,887 (All Physicians)	145,887	2.5	364,717	$14,589	$61,797,674
2021	116,709*** (Additional burden for Subset of Physicians with Websites)	116,709	1	116,709	-	$13,278,038
-	-	Total	3.5	481,426	-	$75,075,712****

*HHS estimates that 80 percent (116,709) of individual physician practitioners have a website. Therefore, estimated cost includes computer programming cost to update individual physician practitioners' websites with right to good faith estimate notice to uninsured (or self-pay) individuals. HHS assumes that each individual physician practitioner will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Total printing and material costs of $14,589 are included.

**The 6-month amount is also calculated to be $75,075,712 for purposes of this emergency PRA package. The cost does not change whether calculated over a twelve or six month timeframe.

***Note that the 116,709 computer programmers are accounted for in the total number of 145,887 individual physician practitioners that must comply with the requirement.

**** This is calculated as the sum of $75,075,712(cost for individual physician practitioners to draft notice of right to GFE) + $13,278,038 (cost for computer programmers to post notice of right to GFE on 80% of practitioners' websites).

Wholly-Physician-Owned Private Practices

HHS estimates that 120,525 wholly physician-owned private practices will incur burden and cost to comply with this provision.[9] For each practice, HHS estimates an average of two hours and thirty minutes for a general and operations manager to read and understand the provided notice and draft any additions in clear and understandable language and a computer programmer one hour to post the information in the provider's website. This results in an equivalent cost of approximately $50,650,005 to be incurred as a one-time cost in 2021.[10]

HHS assumes that each the wholly physician-owned private practice will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. This results in a one-time equivalent cost of approximately $12,052 to all wholly physician-owned private practices.

HHS estimates that the annual one-time burden for wholly physician-owned private practices to develop, prepare, print, and post the notices, and make website updates will be approximately 421,837 total burden hours with an associated equivalent cost of approximately $50,650,005, as shown in Table 6.

*TABLE 6: Estimated One-Time Cost and Hour Burden for Wholly Physician-owned Private Practices to Draft and Post Notice of Good Faith Estimate Notice**

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Burden (Hours)	Printing and Material Cost	Total Estimated Cost**
2021	120,525	120,525	3.5	421,837	$12,052	$50,650,005[11] ***

* Estimated cost includes computer programming cost to update wholly physician-owned private practice website with right of good faith estimate notice to uninsured (or self-pay) individuals. HHS assumes that each the wholly physician-owned private practice will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Total printing and material costs of $12,052 are included.

** The 6-month amount is also calculated to be $50,650,005 for purposes of this emergency PRA package. The cost does not change whether calculated over a twelve or six month timeframe.

***The total estimated cost burden is the sum of $36,925,829 (the cost for wholly physician-owned practices to have a general and operations manager draft and post GFE) + $13,712,123 (the cost

[9] In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf; Professionally Active Physicians. KFF. Published May 20, 2020. https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22.

[10] The burden is estimated as follows: 125,525 wholly physician-owned private practices x 2.5 hours = 301,312 hours. A labor rate of $122,55 is used for a general and operations manager. The labor rate is applied to the following calculation: 120,525 wholly physician-owned private practices x 2.5 hours x $122.55 = $36,925,829. 120,525 wholly physician-owned private practices x 1 hour = 120,525 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 120,525 wholly physician-owned private practices x 1 hour x $113.77 = $13,712,123. Therefore, the total burden hours are

[11] 301,312 + 120,525 = 421,837 and the total equivalent costs are $36,925,829 + $13,712,123 = $50,637,952. The printing and material costs are $12,052. Therefore, $50,637,952+ $12,052 = $50,650,005.

for a computer programmer to update the practice website) + $12,052 (the cost for printing and materials) = $50,650,005. These costs represent 3.5 burden hours per response.

Summary

HHS estimates that the one-time burden for health care providers (including providers associated with health care facilities, individual physician practitioners, and wholly physician-owned private practices) and health care facilities to provide notice of the right to a good faith estimate of expected charges to uninsured (self-pay) individuals will be approximately 2,743,283 total burden hours with an associated equivalent cost of approximately $320,250,169.

*TABLE 7: Estimated Total One-Time Cost Related to Notice of Right to Good Faith Estimate**

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)[12]	Total Annual Labor Burden (Hours)	Total Printing and Material Costs	Total Estimated Cost**
2022	511,748	511,748	15.5	2,743,283	$52,393	$320,250,169

*Tables 32, 33, and 34 are combined to present total estimated amounts. Calculations for the total annual labor burden (in hours) are presented in Tables 4, 5, and 6. This table presents a cumulative 15.5 hours of burden per response for summary purposes.

**The 6-month amount is also calculated to be $320,250,169 for purposes of this emergency PRA package. The cost does not change whether calculated over a twelve or six month timeframe.

12.2 *ICRs Regarding Requirements for Provision of Good Faith Estimate of Expected Charges upon Request of Uninsured (or self-pay) Individuals and for Scheduled Items and Services (45 CFR 149.610)*

These interim final rules require a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request (45 CFR 149.610) including those items or services furnished by a co-provider or co-facility in conjunction with the primary items or services. HHS estimates that approximately 3,498,942 uninsured (or self-pay) individuals will be impacted by this rule requirement.[13] A total of 511,748 providers associated with health care facilities, individual physician practitioners, and wholly physician-owned

[12] This includes the time for providers associated with health care facilities to enter into agreements with health care facilities to provide good faith estimates on their behalf.

[13] 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 populations will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS also assumes a 5% adjustment for good faith estimate inquires only resulting in a final value of 3,498,942. See Squitieri, Lee et al. "Resuming Elective Surgery during Covid-19: Can Inpatient Hospitals Collaborate with Ambulatory Surgery Centers?." *Plastic and reconstructive surgery. Global open* vol. 9,2 e3442. 18 Feb. 2021, doi:10.1097/GOX.0000000000003442 (The study estimates 4,297,850 nonemergency elective procedures (surgical and non-surgical) are performed each month. This value was multiplied by 12 months = 51,574,200. HHS adjusted by approximately one-third of one percent to account annual increase in volume since study publication resulting in 51,744,200). See also KFF Health Insurance Coverage of the Total Population.

private practices will incur the burden and costs associated with generating a good faith estimate.[14] HHS welcomes comments on this estimate.

HHS estimates that it will take an average of 30 minutes for a business operations specialist to determine a patient's insurance status, orally inform the patient of their right to receive a good faith estimate of expected charges, and provide an oral good faith estimate, if no additional items and services are needed. HHS assumes 1,749,471 (50 percent) of uninsured (or self-pay) individuals fall in this category. Therefore, the annual equivalent cost estimate for provision of good faith estimates where no additional items and services are needed is of $88,628,201.[15]

HHS estimates that it will take an average of 30 minutes for a business operations specialist to generate a good faith estimate of expected charges furnished by a co-provider and co-facility for items and services to the convening provider. Given that 1,749,471 (50 percent) of uninsured individuals require additional items and services, the same number (1,749,471) of claims will be generated by co-providers or co-facilities. Therefore, the annual equivalent cost estimate for good faith estimates sent to convening providers by co-providers or co-facilities is $88,628,201.[16] HHS assumes that all communication between convening provider and convening facility, and co-provider or co-facility will be done electronically. Thus, the cost to generate a good faith estimate for both cases where additional items and services are needed and where no additional items and services are needed is $354,512,803.[17]

HHS estimates that it will take an average of one hour for a business operations specialist to determine a patient's insurance status, inform uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges, and provide a good faith estimate, if additional items and services are needed from a co-provider or co-facility. HHS assumes 1,749,471 (50 percent) of uninsured individuals fall in this category. Therefore, the annual equivalent cost estimate is $177,256,402.[18] Thus, a total of $265,884,603 is estimated for business operations specialists, when adding the cost if no additional items and services are needed ($88,628,201) to the cost of items and services from co-providers and co-facilities ($177,256,402).

HHS estimates that approximately 90 percent of uninsured (or self-pay) individuals will receive a good faith estimate of expected charges through the mail that is two pages in length.[19] The remaining 10 percent of uninsured (or self-pay) individuals will receive the good faith estimate via email correspondence; burden and costs are therefore accounted for in the two preceding paragraphs. HHS assumes that each convening provider or facility will incur a printing cost of $0.05 per page and materials

[14] These estimates include the total number of health care facilities and health care providers from the preceding ICR Regarding Notice of Right to Good Faith Estimate.

[15] The burden is estimated as follows: 1,749,471 uninsured individuals in need of good faith estimates without additional items and services x 0.50 hours = 874,736 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims x 0.50 hours x $101.32 = $88,628,201.

[16] The burden is estimated as follows: 1,749,471 uninsured individuals in need of good faith estimates with additional items and services x 0.50 hours = 874,736 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims x 0.50 hours x $101.32 = $88,628,201.

[17] The burden is estimated as follows: $88,628,201 + $177,256,402 + $88,628,201 = $354,512,803.

[18] The burden is estimated as follows: 1,749,471 claims x 1 hour = 1,749,471 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims x 1 hour x $101.32 = $177,256,402.

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

for a total equivalent cost of $0.10 per good faith estimate. Therefore, the annual equivalent cost estimate for printing good faith estimates is $314,905 for all health care providers and health care facilities.[20]

HHS assumes that 5 percent of uninsured (or self-pay) individuals (i.e., 157,452 uninsured (or self-pay) individuals) will request a mailed copy of their written good faith estimate of expected charges to a preferred location.[21] HHS assumes that it will take an average of fifteen minutes for a medical secretary and administrative assistant to print and mail the good faith estimate to the uninsured (or self-pay) individual. HHS estimates a postage cost of $0.55 per mailing. Therefore, the annual equivalent cost estimate is $1,900,057 to mail the good faith estimate for all health care providers and health care facilities.[22]

TABLE 8: Estimated Annual Cost and Hour Burden per Response per Health Care Provider and Health Care Facility to Accept and Fulfill Requests for Mailed Good Faith Estimates of Expected Charges (Mailing Costs Only)

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Mailing Cost per Respondent
Medical Secretary and Administrative Assistant	0.25	$46.07	$3.71[23]
Total per Respondent	0.25	-	$3.71

TABLE 9: Estimated Annual Cost and Hour Burden for All Health Care Providers and Health Care Facilities to Accept and Fulfill Requests for Mailed Good Faith Estimates of Expected Charges

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Labor Costs of Reporting	Mailing Cost	Total Annual Cost*
511,748	157,452	0.25	39,363	$1,813,458	$86,599	$1,900,057[24]

*The 6-month amount is calculated to be $ 950,028.50 over the period January 1, 2022 through June 30, 2022 for purposes of this emergency PRA package. The burden is estimated as follows: 157,452 good faith estimates x 0.25 hours = 39,363 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 157,452 good faith estimates x 0.25 hours x $46.07 =$1,813,458. Therefore, 157,452 mailed good faith estimates x $0.55 postage cost = $86,599 in mailing costs + $1,813,458 in annual respondent time cost = $1,900,057.

Summary

[20] The estimate is calculated as follows: $0.05 cost per page x 2 pages x 3,149,048 uninsured individuals who receive a written good faith estimate = $314,905.

[21] An estimated 3,149,048 uninsured individuals who receive a written good faith estimate x 5% =157,452 uninsured individuals who request a mailed good faith estimate of expected charges.

[22] The burden is estimated as follows: 157,452 good faith estimates x 0.25 hours = 39,363 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 157,452 good faith estimates x 0.25 hours x $46.07 =$1,813,458.

[23] The cost per respondent is calculated as: $1,900,057 in medical secretary and administrative assistant annual respondent time cost to mail good faith estimate and mailing costs (printing costs are already accounted for in preceding section) divided by 511,748 health care providers and healthcare facilities = $3.71 cost per respondent.

[24] Therefore, 157,452 mailed good faith estimates x $0.55 postage cost = $86,599 in mailing costs + $1,813,458 in annual respondent time cost = $1,900,057.

HHS estimates the annual cost to a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request between 2022-2024 to be $356,727,765 (inclusive of printing, materials, mailing costs) and total burden hours of 3,538,305.

HHS estimates the annual cost for printing and materials to provide a written good faith estimate to uninsured individuals to be $314,905. The mailing costs of good faith estimates to uninsured (or self-pay) individuals is $86,599 with an annual total burden hour estimate of 39,363 hours and a total annual respondent time cost of $1,813,458. This estimate is included in the total cost of $356,727,765 . The estimated cost over the 6-month period January 1, 2022 through June 30, 2022 is $178,363,882, or half the annual amount as calculated for purposes of this emergency PRA package. HHS invites comment on the assumptions and calculations made in this ICR.

TABLE 10: Annual Burden and Total Cost Related to Provision of Good Faith Estimates for Uninsured (or-Self-Pay) Individuals (Labor, Printing, and Mailing)

Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Annual Respondent Time Cost	Printing and Mailing Costs (Labor Cost Included)*	Total Estimated Cost**
3,498,942	3,498,942	2.0	3,498,942	$354,512,803	$2,214,961	$356,727,765***

* This is calculated as following: $314,905 in printing costs + $86,599 in mailing costs + $1,813,458 in estimated annual respondent time cost to mail good faith estimate = $2,214,961. HHS assumes that it will take an average of fifteen minutes for a medical secretary and administrative assistant to print and mail the good faith estimate to the uninsured (or self-pay) individual. The annual burden hours associated with printing and mailing a good faith estimate of expected charges is 39,363 hours.
**The 6-month amount is calculated to be $178,363,882 over the period January 1, 2022 through June 30, 2022 for purposes of this emergency PRA package.
*** The total estimated cost burden is the sum $88,628,201 (the GFE costs without co-providers or co-facilities) + $177,256,402 (the GFE costs with co-providers or co-facilities) + $88,628,201 (the GFE costs to convening providers) + $2,214,961 (printing and mailing costs, including labor).

12.3 *ICRs Regarding Patient-Provider Dispute Resolution Process (45 CFR 149.620)*

These interim final rules enable uninsured (or self-pay) individuals to initiate a patient-provider dispute resolution process if their final billed charges are in excess of the expected charges in the good faith estimate supplied by the provider or facility by at least $400 more than the amount listed in the good faith estimates supplied by the provider or facility. HHS does not have data on how many claims will be likely to 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.[25] 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

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

Departments estimate that there will be 26,659 claims that result in patient-provider dispute resolution each year. [26]

HHS estimates that it will take an average of 2 hours for an uninsured (or self-pay) individual or, if they use an authorized representative, 1 hour for their authorized representative to write, prepare, 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 $3,789,694.[27] 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. 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 $12,193.[28,29] 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

[26] 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.

[27] The burden is estimated as follows: 26,659 x 90% = 23,993 uninsured (or self-pay) individuals will self-represent. 23,993 x 2 hours = 47,986 hours. A labor rate of $64.32 is used for uninsured (or self-pay) individuals (all occupations). The labor rate is applied in the following calculation: 23,993 claims x 2 hours x $64.32 = $3,086,427. HHS assumes that uninsured (or self-pay) individual will appoint an authorized representative in 10% of cases. 26,659 x 10% = 2,666 claims represented by an authorized representative. Therefore, the burden estimate is estimated as follows: 2,666 claims represented by lawyers x 1 hour = 2,666 hours. A labor rate of $140.96 is used for a lawyer. The labor rates are applied in the following calculation: 2,666 claims x 1 hour x $140.96 = $375,785. HHS assumes approximately 15% of uninsured (or self-pay) individuals 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 claims x 10% = 2,399 resubmitted claims by individual x 2 hours x $64.32 (labor rate) = $129,899. 2,666 claims x 5% = 133 resubmitted claims by authorized representative x 1 hour x $140.96 (labor rate) = $18,789. The total annual respondent time cost estimates are added as follows: $3,086,472 + $375,785 + $308,647 + $18,789 = $3,789,694. The total burden hours are 55,584.

[28] 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 $0.55 in postage cost. Therefore, $0.05 cost per page x 3 pages x 17,419 mailed initiation notices (inclusive of notices that needed to be resubmitted) = $2,613 in printing and material costs. The postage costs are calculated as $0.55 cost per postage x 17,419 mailed initiation notices = $9,580 in postage cost. The total printing and materials and postage costs are therefore $2,613 + 9,580 = $12,193.

[29] 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.

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 $7,024,811 as shown in table 11.[30]

TABLE 11: Estimated Annual Cost and Hour Burden Related to Attestation of Conflict of Interest with a Patient-Provider Dispute Resolution Initiation Notice

Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
26,659	26,659	2	53,317	$7,024,811

These interim final rules also require the selected 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) 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 $3,267,013.[31]

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

[30] The burden is estimated as follows: 26,659 claims x 1 hour = 26,659 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims x 1 hour x $122.55 = $3,267,013. The burden for legal review is estimated as follows: 26,659 claims x 1 hour = 26,659 hours. A labor rate of $140.96 is used for a lawyer. The labor rates are applied in the following calculation: 26,659 claims x 1 hour x $140.96 = $3,757,798. The total annual response time cost estimates are added as follows: $3,267,013 + $3,757,798 = $7,024,811. The total burden hours are 53,317.

[31] The burden is estimated as follows: 26,659 claims x 1 hour = 26,659 hours. A labor rate of $101.32 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims x 1 hour x $122.55 = $3,267,013. Total burden hours are 26,659 hours.

VI.B.7 of the preamble. The SDR entity must respond within 30 days after receipt information from the provider or facility to make determinations on charges to the uninsured (or self-pay) individual. 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 $14,049,622.[32]

Table 12. Estimated annual burden to assess the submitted information and determine a prevailing party

Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
26,659	26,659	4	106,634	$14,049,622

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 $1,633,506.[33]

The SDR entity must also submit the administrative fee to the Secretary of HHS on behalf of uninsured (or self-pay) individuals and the provider or facility. This burden includes time to review instructions, search existing data resources, gather data needed, and complete and review 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 $2,982.42, as shown in table 13.[34] HHS estimates the total annual ongoing costs associated with implementation and the administration of the patient-provider dispute resolution 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 $655,475 and a total annual cost to the federal government of $12 million.

[32] The burden is estimated as follows: 26,659 claims x 2 hours = 53,317 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims x 2 hours x $122.55 = $6,534,026. The burden for legal review is estimated as follows: 26,659 claims x 2 hours = 53,317 hours. A labor rate of $140.96 is used for a lawyer. The labor rates are applied in the following calculation: 53,317 x 2 hours x $140.96 = $7,515,596. The total annual respond time cost estimates are calculated as follows: $6,534,026 + $7,515,596 = $14,049,622. The total annual burden hours are 106,634 hours.

[33] The burden is estimated as follows: 26,659 claims x 0.50 hours = 13,329 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims x 0.50 hours x $122.55= $1,633,506.

[34] The burden is estimated as follows: A labor rate of $55.23 is used for a clerical worker. The labor rate is applied in the following calculation: 3 annual responses x 18 hours x $55.23 = $2,982.42.

TABLE 13: Estimated Annual Burden and Cost Related to SDR Submission of the Administrative fee to HHS.

Estimated Number of Responses	Total Annual Burden (1.5 hours x 12 months)	Annual Cost Per IDR entity	Annual Cost for all Responses
3	18	994.14	$2,982.42

Summary

The total annual burden associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals and providers and facilities is 255,524 hours with an equivalent cost of $29,764,646, as shown in Table 14.[35] The estimated cost over the 6-month period January 1, 2022 through June 30, 2022 is $ 14,882,323 or half the annual amount as calculated for purposes of this emergency PRA package. HHS invites comment on the assumptions and calculations made in this ICR.

TABLE 14: Annual Burden and Cost Related to Patient-Provider Dispute Resolution Process for Uninsured (Self-Pay) Individuals and Providers and Facilities

Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost*†
26,659	26,659	13.50	255,524	$29,764,646

*The 6-month amount is calculated to be $14,882,323 over the period January 1, 2022 through June 30, 2022 for purposes of this emergency PRA package.
These costs represent a cumulative total of 13.5 burden hours per response (9.6 hours per response on average) for summary purposes. The total 255,524 hours is the amount for total costs.

12.4 *ICRs Regarding Patient-Provider Dispute Resolution Entity Certification (45 CFR 149.620)*

An SDR entity must be certified under standards and procedures set forth in guidance promulgated by the Secretary. HHS estimates that there will be between 1 and 3 entities that HHS contracts with to be an SDR entity.

[35] The total estimated cost burden is the sum of $3,789,694 (the cost for uninsured or self-pay individuals and authorized representatives to write, prepare and send the initiation notice for the patient-provider dispute resolution to the Secretary, including resubmission costs) + $7,024,811 (the cost for SDR entities to attest whether a Conflict of Interest exists with the uninsured or self-pay individual, provider or facility) + $3,267,013 (the cost for uninsured or self-pay individuals and providers or facilities to furnish additional information to selected SDR entities) + $14,049,622 (the cost for the SDR entity to carry out the dispute outcome analysis for uninsured or self-pay individuals and providers and facilities) + 1,633,506 (the cost for the SDR entity to notify the parties of the SDR entity's determination) = $29,764,646. These costs represent 13.5 burden hours.

To be an SDR entity, the entity will need to establish the processes and complete the corresponding paperwork. HHS estimates that on average it will take a general and operations manager five hours and medical secretary and administrative assistant 15 minutes to satisfy the requirement. As shown in Table 15, this result in an equivalent cost burden of $1,554 in the first year.[36]

TABLE 15: Estimated First Year One-Time Cost Annual Burden and Cost Related to Patient-Provider SDR Entity Certification Process Cost Related to Patient-Provider Dispute Resolution Process

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost*
2022	3	3	5.25	15.75	$1,873

*The 6-month amount is also calculated to be $1,554 for purposes of this emergency PRA package. The cost does not change whether calculated over a twelve or six month timeframe.

HHS estimates that on average one-third of SDR entities (i.e., one of the three contracted organizations) will need to be recertified or reapproved, through the contracting process, each year and that on average it will take a general and operations manager two hours and medical secretary and administrative assistant 15 minutes to satisfy the requirement. This results in an equivalent cost burden of $257.[37]

The total annual burden associated with the patient-provider SDR entity certification is 16 hours with an equivalent cost of $1,873. In subsequent years, the total hour burden associated with the patient-provider SDR entity certification or re-approval is 2.25 hours with an equivalent cost of $257. HHS invites comment on the assumptions and calculations made in this ICR.

TABLE 16: Annual Burden and Cost Related to Patient-Provider SDR Entity Re-Certification Process

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost*
2023	1	1	2.25	2.25	$257

[36] The burden is estimated as follows: (3 SDR entities x 5 hours) + (3 SDR entities x 0.25 hours) = 15.75 hours. A labor rate of $122.55 is used for a general and operations manager and a labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rates are applied in the following calculation: (3 SDR entities x 5 hours x $122.55) + (3 SDR entities x 0.25 hours x $46.07) = $1,873.

[37] The burden is estimated as follows: (1 SDR entity x 2 hours) + (1 SDR entity x 0.25 hours) = 2.25 hours. A labor rate of $122.55 is used for a general and operations manager and a labor rate of $46.07 is used for medical secretary and administrative assistant. The labor rates are applied in the following calculation: (1 SDR entity x 2 hours x $122.55) + (1 SDR entity x 0.25 hours x $46.07) = $257.

* The 6-month amount is also calculated to be $257 for purposes of this emergency PRA package. The cost does not change whether calculated over a twelve or six month timeframe.

HHS will assess the SDR entity's standards as part of contracting per the contract period.

13 Capital Costs

HHS assumes in the ICR for patient-provider dispute resolution that 34 percent of initiation notices will be sent electronically and 66 percent of the initiation notices will be mailed with an associated printing and materials and postage costs of $55,423. HHS assumes that the average initiation notice sent via mail will be 3 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 $0.55 in postage cost. Therefore, $0.05 cost per page x 3 pages x 79,176 mailed initiation notices = $11,876 in printing and material costs. The postage costs are calculated as $0.55 cost per postage x 79,176 mailed initiation notices = $43,547 in postage cost. The total printing and materials and postage costs are therefore $11,876 + $43,547 = $55,423.

14 Cost to Federal Government

Total costs to the Federal Government are listed below.

14.1 *Provider-Payer Dispute Resolution Platform/Portal*

Costs to the federal government to build the federal IDR portal are estimated to be one-time costs of $6 million in FY 2021; and annual ongoing costs to maintain the portal, are estimated to be approximately $1 million beginning in 2022.

14.2 *Patient-Provider Dispute Resolution Process*

HHS estimates the total annual ongoing costs associated with implementation and the administration of the SDR 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 $655,475 and a total 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).