

Supporting Statement - Part A
Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in (CMS-10780/OMB control number: 0938-NEW)

A. Background

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA),¹ which included 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.

A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a participant, beneficiary, or enrollee receives medical services from a provider (including a provider of air ambulance services) or facility that, generally unbeknownst to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage. Surprise billing occurs both for emergency and non-emergency care. In an emergency, a person usually goes (or is taken by emergency transport) to a nearby emergency department. Even if they go to a participating hospital or facility for emergency care, they may receive care from nonparticipating providers working at that facility. For non-emergency care, a person may choose a participating facility (and possibly even a participating provider), but not know that at least one provider involved in their care is a nonparticipating provider. In either circumstance, the person might not be in a position to choose the provider, or to ensure that the provider is a participating provider. Therefore, in addition to a bill for their cost-sharing amount, which tends to be higher for out-of-network services, the person might receive a balance bill from the nonparticipating provider or facility. This scenario also plays out frequently for air ambulance services, where individuals generally do not have the ability to select a provider of air ambulance services, and, therefore, have little or no control over whether the provider is in-network with respect to their plan or coverage.

The 2021 interim final regulations "Requirements Related to Surprise Billing; Part I" (86 FR 36872, henceforth 2021 interim final regulations) issued by the Departments of Health and Human Services (HHS), Department of Labor (DOL), the Department of Treasury (collectively, the Departments), and the Office of Personnel Management implement provisions of the No Surprises Act that apply to group health plans, health insurance issuers offering group or individual health insurance coverage, and carriers in the Federal Employees Health Benefits Program that provide protections against balance billing and out-of-network cost sharing with respect to emergency services, non-emergency services furnished by nonparticipating providers at certain participating health care facilities, and services furnished by nonparticipating providers of air ambulance services. The 2021 interim final regulations prohibit nonparticipating providers, emergency facilities, and providers of air ambulance services from balance billing participants, beneficiaries, and enrollees in certain situations unless they satisfy certain notice and consent requirements;

¹ Pub. L. 116-260.

and require health care facilities and providers to provide disclosures of federal and state patient protections against balance billing.

Section 9816(a)(1)(C)(iii) of Internal Revenue Code (the Code), section 716(a)(1)(C)(iii) of the Employee Retirement Income Security Act (ERISA), section 2799A-1(a)(1)(C)(iii) of the Public Health Service Act (PHS Act), and the 2021 interim final regulations specify that for emergency services furnished by a nonparticipating emergency facility or provider, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, an individual's cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for such services, as defined by the statute and in the 2021 interim final regulations.

The "recognized amount" is: (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no applicable All-Payer Model Agreement or specified state law, the lesser of the amount billed by the provider or facility or the qualifying payment amount (QPA), which under the 2021 interim final regulations is generally the median of the contracted rates of the plan or issuer for the item or service in the geographic region. For air ambulance services, an individual's cost sharing is calculated using the lesser of the amount billed by the provider of air ambulance services or the QPA.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA), the Centers for Medicare & Medicaid Services (CMS) has submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting emergency review and approval of the information collection request related to provisions in the No Surprises Act. In accordance with 5 CFR 1320.13(a)(2)(i), we believe that public harm will result if the standard, non-emergency clearance procedures are followed.

B. Justification

1. Need and Legal Basis

The 2021 interim final regulations at 45 CFR 149.140(d) require group health plans and group and individual health insurance issuers to provide certain information regarding the QPA to nonparticipating providers, or nonparticipating emergency facilities in cases in which the recognized amount with respect to an item or service furnished by the provider or facility is the QPA (and in all cases subject to these rules for nonparticipating providers of air ambulance services). Specifically, plans and issuers must provide the following information to providers (including air ambulance providers) and facilities, when making an initial payment or notice of denial of payment: (1) the QPA for each item or service involved; (2) a statement certifying that the plan or issuer has determined that the QPA

applies for the purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and that each QPA was determined in compliance with the methodology established in the 2021 interim final regulations; (3) a statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and (4) contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service. Additionally, upon request of the provider or facility, the plan or issuer must provide, in a timely manner, the following information: (1) whether the QPA for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services, and whether the QPA for those items and services was determined using underlying fee schedule rates or a derived amount; (2) if a related service code was used to determine the QPA for a new service code, information to identify the related service code; (3) if the plan or issuer used an eligible database to determine the QPA, information to identify which database was used; and (4) if applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, or other incentive-based or retrospective payments or payment adjustments for covered items and services that were excluded for purposes of calculating the QPA.

The No Surprises Act provides that rulemaking must establish a process under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the applicable Secretary or applicable state authority to ensure that such plans and coverage are in compliance with the requirement of applying a QPA and that the QPA applied satisfies the definition under the No Surprises Act with respect to the year involved.

The 2021 interim final regulations at 45 CFR 149.140(f) include an audit provision establishing that the Departments' existing enforcement procedures will apply with respect to ensuring that a plan or coverage is in compliance with the requirement of determining and applying a QPA consistent with the 2021 interim final regulations. Pursuant to section 2723(a)(1) of the PHS Act, as amended by the No Surprises Act, states have primary enforcement authority over health insurance issuers regarding the provisions of Parts A and D of title XXVII of the PHS Act. Under this framework, HHS has enforcement authority over issuers in a state if the HHS Secretary makes a determination that the state is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act.²

² Section 2723(a)(2) and (b)(1)(A) of the PHS Act. *See also* 45 CFR 150.203.

The 2021 interim final regulations allow self-insured group health plans, including self-insured non-federal governmental plans, to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)-(d) of the Code, section 716(a)-(d) of ERISA, and section 2799A-1(a)-(d) of the PHS Act. As required by 45 CFR 149.30, a self-insured plan that has chosen to opt in to a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted in to a specified state law, identify the relevant state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

The No Surprises Act and the 2021 interim final regulations require that a plan or issuer providing coverage of emergency services do so without the individual or the health care provider having to obtain prior authorization and without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services (regardless of the department of the hospital in which such items and services are furnished). Emergency services include any additional items and services that are covered under a plan or coverage after a participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the other emergency services are furnished (referred to as post-stabilization services) unless certain notice and consent requirements are met. The No Surprises Act and the 2021 interim final regulations further apply surprise billing protections in the case of non-emergency services furnished by nonparticipating providers during a visit by a participant, beneficiary, or enrollee at participating health care facilities unless notice and consent as specified in the 2021 interim final regulations have been met. The requirements related to the notice and consent, applicable exceptions, and timing are set forth in section 2799B-2 of the PHS Act, and implemented at 45 CFR 149.410 and 45 CFR 149.420 of the 2021 interim final regulations.

In addition to providing the required notice and consent, nonparticipating emergency facilities, participating health care facilities, and nonparticipating providers are obligated to retain written notice and consent documents for at least a 7-year period after the date on which the item or service in question was furnished. Where the notice and consent requirements described in the 2021 interim final regulation have been met, the nonparticipating provider, the participating health care facility on behalf of the nonparticipating provider, or the nonparticipating emergency facility, as applicable, must timely notify the plan or issuer, respectively, that the notice and consent criteria have been met, and if applicable, provide to the plan or issuer a signed copy of the notice and consent documents. In addition, for items and services furnished by a nonparticipating provider at a participating health care facility, the provider (or the participating facility on behalf of the provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility.

Section 2799B-3 of the PHS Act, as added by the No Surprises Act and codified at 45 CFR 149.430, requires providers and facilities to provide disclosures regarding patient protections against balance billing. Specifically, health care providers and facilities (including an emergency department of a hospital or independent freestanding emergency department) are required to make publicly available, post on a public website of the provider or facility, and provide to participants, beneficiaries, and enrollees a one-page notice about surprise billing protections. The required notice must include clear and understandable language that explains the requirements and prohibitions relating to the prohibitions on balance billing in cases of emergency services and in cases of non-emergency services performed by a nonparticipating provider at certain participating facilities, explain any other applicable state laws, and provide contact information for the appropriate state and federal agencies that an individual may contact if they believe the provider or facility has violated a requirement described in the notice.

Section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act require plans and issuers to make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act apply, information in plain language on the provisions in those sections, and sections 2799B-1 and 2799B-2 of the PHS Act, and other applicable state laws on out-of-network balance billing, as well as information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing.

2. **Information Users**

The information regarding QPA provided by plans and issuers to nonparticipating providers and nonparticipating emergency facilities will provide transparency regarding how the QPA was determined. For self-insured plans that opt in to state law, the disclosure regarding the opt-in will provide information to participants and beneficiaries regarding the applicable protections against surprise medical bills.

The notice and consent documents and disclosures on balance billing protections provided by plans and issuers and nonparticipating providers and facilities will provide information to participants, beneficiaries, or enrollees regarding the protections against surprise medical bills. The requirements related to the notice and consent documents will help ensure that individuals are not pressured to waive their rights and that individuals will only waive their rights if they wish to obtain the services of a nonparticipating provider for a specific reason. Plans and issuers will be provided the information they need in order to determine if balance billing protections apply to specific items and services provided by a nonparticipating provider or nonparticipating emergency facility or if the enrollee provided consent to waive those protections.

3. **Use of Information Technology**

The documents related to QPA will be provided electronically by plans and issuers to nonparticipating providers and nonparticipating emergency facilities. The notice and consent documents may be provided electronically as selected by the individual. The disclosures related to balance billing protections provided by plans and issuers and nonparticipating providers and nonparticipating emergency facilities may also be provided electronically.

4. **Duplication of Efforts**

There is no duplication of efforts for these information collection requirements (ICRs).

5. **Small Businesses**

Health care facilities incurring burden related to these ICRs include ambulatory surgical centers, hospitals and free-standing emergency departments. It is likely that almost 54 percent of individual ambulatory surgical centers and free-standing emergency departments will qualify as small entities, though some of them are part of larger systems. For hospitals, approximately 18 percent of individual hospitals are estimated to be small entities,³ though some of them may be part of larger hospital systems that are not small businesses. The Departments have made an effort to minimize the burden on all respondents. The average cost of compliance for each health care facility is estimated to be approximately \$5,300 annually over 3 years.

6. **Less Frequent Collection**

If this information collection is conducted less frequently, individuals will not have information regarding their protection against surprise medical bills. Additionally, without the information on whether individuals provided consent to be treated by nonparticipating providers or nonparticipating emergency facilities, plans and issuers will not be able to properly determine cost sharing for participants, beneficiaries and enrollees. Without timely notification from plans and issuers of how they determined the QPA, providers will not be able to determine whether it is in their best interest to accept a plan's or issuer's initial payment amount, as payment in full (including a participant's, beneficiary's or enrollee's cost sharing).

7. **Special Circumstances**

There are no special circumstances.

³ Based on data from 2017 Statistics of U.S. Businesses. Available at <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.

8. **Federal Register/Outside Consultation**

An interim final rule with requests for comment (86 FR 36872) was published on July 13, 2021.

9. **Payments/Gifts to Respondents**

No payments or gifts are associated with these ICRs.

10. **Confidentiality**

Privacy of the information provided will be protected to the extent provided by law.

11. **Sensitive Questions**

These ICRs involve no sensitive questions.

12. **Burden Estimates (Hours & Wages)**

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.⁴ Table 1 below presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage. As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent.

TABLE 1: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hour)	Fringe Benefits and Overhead (\$/hour)	Adjusted Hourly Wage (\$/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43-6014	\$19.43	\$19.43	\$38.86
Lawyer	23-1011	\$71.59	\$71.59	\$143.18
All Occupations	00-0000	\$27.07	\$27.07	\$54.14
Computer Programmers	15-1251	\$45.98	\$45.98	\$91.96
Medical Secretaries and Administrative Assistants	43-6013	\$18.75	\$18.75	\$37.50
Computer and Information Systems Managers	11-3021	\$77.76	\$77.76	\$155.52

⁴ See 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.

1. ICRs Regarding Information to be Shared About QPA (45 CFR 149.140(d))

The 2021 interim final regulations require plans and issuers to provide certain information regarding the QPA to nonparticipating providers, or nonparticipating emergency facilities in cases in which the recognized amount with respect to an item or service furnished by the provider or facility is the QPA (and in all cases subject to these rules for nonparticipating providers of air ambulance services).

The Departments assume that third party administrators (TPAs) will provide this information on behalf of self-insured plans. In addition, HHS assumes that issuers and TPAs will automate the process of preparing and providing this information in a format similar to an explanation of benefits as part of the system to calculate the QPA.

The Departments estimate that a total of 1,758 entities – 1,553 issuers⁵ and 205 TPAs⁶ – will incur burden to comply with this provision. Currently, 14 states have established some payment standards for services provided by nonparticipating providers or nonparticipating emergency facilities. Therefore, the Departments assume that issuers and TPAs will potentially need to calculate the QPA for two-thirds of the claims involving nonparticipating providers or nonparticipating emergency facilities.

In 2018, there were approximately 39,690,940 emergency department visits for patients with individual market or group health coverage.⁷ The Departments estimate that approximately 18 percent of these visits⁸ will include services provided by nonparticipating providers or nonparticipating emergency facilities and plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the specified information along with the initial payment or denial notice for approximately 4,786,727 claims annually from nonparticipating providers or nonparticipating emergency facilities for emergency department visits. In addition, in 2018, there were approximately 4,146,476 emergency department visits that resulted in hospital admission for patients with individual market or group health coverage. Using this as an estimate of post-stabilization services provided in emergency facilities, and assuming that in 16 percent of cases the patient is treated at a nonparticipating emergency facility or by a nonparticipating provider

⁵ Based on data from MLR annual report for the 2019 MLR reporting year, available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

⁶ Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

⁷ Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits.

<https://www.hcup-us.ahrq.gov/faststats/NationalTrendsEDServlet?measure1=01&characteristic1=14&measure2=&characteristic2=11&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide>

⁸ Estimate from Pollitz, K et al., Surprise Bills Vary by Diagnosis and Type of Admission, Peterson-KFF Health System tracker, December 9, 2019, <https://www.healthsystemtracker.org/brief/surprise-bills-vary-by-diagnosis-and-type-of-admission/>

at a participating facility,⁹ the Departments estimate that approximately 663,436 individuals will have the potential to be treated by a nonparticipating provider or facility. In the absence of data, the Departments assume that in 50 percent of cases services will be provided by nonparticipating providers without satisfying the notice and consent criteria in the 2021 interim final regulations for reasons such as unforeseen, urgent medical needs or lack of participating providers in the facility. The Departments estimate that plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the required information along with the initial payment or denial notice for approximately 222,251 claims from nonparticipating providers or nonparticipating emergency facilities for post-stabilization services. Additionally, based on 2016 data, the Departments estimate that there will be 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures for individuals with group health coverage or individual market coverage.¹⁰ The Departments assume that in 16 percent of cases the patient will have the potential to receive care from a nonparticipating provider at a participating facility, and that in approximately 5 percent of those cases services will be provided by nonparticipating providers without satisfying the notice and consent criteria in the 2021 interim final regulations for reasons such as the services being ancillary services or related to unforeseen, urgent medical needs, and plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the required information along with the initial payment or denial notice for approximately 59,534 claims annually for non-emergency services furnished by a nonparticipating provider at a participating health care facility. In total, plans and issuers will be required to provide documents related to QPAs along with the initial payment or denial of payment for approximately 5,068,512 claims annually from nonparticipating providers or facilities. The Departments estimate that for each issuer or TPA it will take a medical secretary 10 minutes (at an hourly rate of \$37.50) to prepare the documentation and attach it to each payment or denial notice or explanation of benefits sent to the nonparticipating provider or facility. The Departments assume that this information will be sent electronically at minimal cost. The total annual burden for all issuers and TPAs to provide the QPA information and certification along with 5,068,512 payments or denial notices, is estimated to be approximately 844,752 hours, with an associated equivalent cost of approximately \$31.7 million.

The Departments assume that of the approximately 5,068,512 instances in which QPA information is sent to nonparticipating providers or nonparticipating emergency facilities, 50 percent will result in requests to provide additional information and plans and issuers will be required to send additional information to approximately 2,534,256 providers or facilities. The Departments estimate that it will take a medical secretary 15 minutes (at an hourly rate of \$37.50) to prepare the document and provide it to the provider or facility that requested it.

⁹ *Id.*

¹⁰ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

The Departments assume that this information will be delivered electronically with minimal additional cost. The total estimated burden, for all issuers and TPAs, will be approximately 633,564 hours annually, with an associated equivalent cost of approximately \$23.8 million.

The total annual burden for all issuers and TPAs for providing the initial and additional information related to QPA will be 1,478,316 hours, with an equivalent cost of \$55,436,853. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the total burden, or approximately 739,158 burden hours with an equivalent cost of approximately \$27,718,427. The Departments seek comment on these burden estimates.

TABLE 2: Annual Burden and Cost for Plans and Issuers to Provide Information Related to QPA to Nonparticipating Providers and Nonparticipating Emergency Facilities

	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
Initial Information	879	2,534,256	0.167	422,376	\$15,839,101
Additional Information	879	1,267,128	0.25	316,782	\$11,879,326
Total	879	3,801,384		739,158	\$27,718,428

2. ICRs Regarding Audits of QPA (45 CFR 149.140(f))

The No Surprises Act provides that rulemaking must establish a process under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the applicable Secretary or applicable state authority to ensure that such plans and coverage are in compliance with the requirement of applying a QPA and that the QPA applied satisfies the definition under the No Surprises Act with respect to the year involved.

The 2021 interim final regulations include an audit provision establishing that the Departments’ existing enforcement procedures will apply with respect to ensuring that a plan or coverage is in compliance with the requirement of determining and applying a QPA consistent with the 2021 interim final regulations.

HHS has primary enforcement authority over issuers (in a state if the HHS Secretary makes a determination that a state is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act)) and non-federal governmental plans, such as those sponsored by state and local government employers and expects to conduct no more than 9 audits annually. Therefore, this collection is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

3. ICRs Regarding Disclosure for Self-Insured Plans Opting in to State Law (45 CFR 149.30)

A self-insured plan that has chosen to opt in to a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted in to a specified state law, identify the relevant state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

Based on available data, HHS estimates that approximately 84 self-insured non-federal governmental plans in New Jersey, Nevada, Virginia, and Washington¹¹ will opt in and incur the one-time burden and cost to include the disclosure in their plan documents in 2022. It is estimated that for each plan an administrative assistant will spend 1 hour (at an hourly rate of \$38.86) and a compensation and benefits manager will spend 30 minutes (at an hourly rate of \$131.88) to prepare the disclosure. The estimated total burden for each plan will be 1.5 hours with an equivalent cost of approximately \$105. The estimated total annual burden for all 84 plans will be approximately 126 hours with an equivalent cost of approximately \$8,783.

Including the printing and materials costs discussed in the section on capital costs below, the total one-time cost for all plans, incurred in 2022, is estimated to be approximately \$8,981.

TABLE 3: One-time Burden and Cost to Provide Disclosure Regarding Opting in to State Law

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Labor Cost	Total Estimated Printing and Materials Cost	Total Estimated Cost
2022	84	84	1.5	126	\$8,783	\$197	\$8,981

4. ICRs Regarding Notice and Consent to Waive Balance Billing Protections, Retention of Certain Documents, and Notice to Plan or Issuer (45 CFR 149.410(b)-(e), 45 CFR 149.420(c) - (i))

In order to meet the notice and consent requirements of the 2021 interim final regulations, nonparticipating providers and nonparticipating emergency facilities must provide the

¹¹ Based on data on self-insured plans that have opted in available at: <https://www.insurance.wa.gov/self-funded-group-health-plans>, <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>, and <https://scc.virginia.gov/balancebilling>.

participant, beneficiary, or enrollee with a notice, meet certain timing requirements, and obtain consent from the participant, beneficiary, or enrollee as described in 45 CFR 149.410 and 149.420. The provided notice must: (1) state that the health care provider or facility is a nonparticipating provider or facility; (2) include the good faith estimate of what the individual may be charged, including any item or service that is reasonably expected to be provided in conjunction with such items and services; (3) provide information about whether prior authorization or other care management limitations may be required; and (4) clearly state that consent to receive such items or services is optional and that the participant, beneficiary, or enrollee may instead seek care from an available participating provider, in which case the individual's cost-sharing responsibility would be at the in-network level. In cases where post-stabilization services are furnished by a nonparticipating provider at a participating emergency facility, the notice must also include a list of participating providers at the participating emergency facility who are able to furnish the items or services involved and inform the individual that they may be referred, at their option, to such a participating provider. Additionally, a nonparticipating provider or nonparticipating emergency facility must provide the participant, beneficiary, or enrollee, or such individual's authorized representative, with the notice and consent documents in any of the 15 most common languages in the state, or a geographic region that reasonably reflects the geographic region served by the applicable facility. If the individual's preferred language is not among the 15 most common languages made available or the individual cannot understand the language in which the notice and consent document are provided the individual must be provided with a qualified interpreter. HHS is specifying mandatory notice and consent forms that will require customization by the provider or facility. To the extent a state develops notice and consent documents that meet the statutory and regulatory requirements, the state-developed documents will meet the Secretary's specifications regarding the form and manner of the notice and consent documents.

In addition to providing the required notice and consent, nonparticipating emergency facilities, participating health care facilities on behalf of nonparticipating providers, and nonparticipating providers are obligated to retain written notice and consent documents for at least a 7-year period after the date on which the item or service in question was furnished.

Where the notice and consent requirements described in the 2021 interim final regulations have been met, the nonparticipating provider, the participating health care facility on behalf of the nonparticipating provider, or the nonparticipating emergency facility, as applicable, must timely notify the plan or issuer, respectively, that the notice and consent criteria have been met, and if applicable, provide to the plan or issuer a copy of the signed notice and consent documents. In instances where, to the extent permitted by these rules, the nonparticipating provider bills the participant, beneficiary, or enrollee directly, the provider may satisfy the requirement to notify the plan or issuer by including the notice and consent documents with the bill to the participant, beneficiary, or enrollee. In addition, for items and

services furnished by a nonparticipating provider at a participating health care facility, the provider (or the participating facility on behalf of the provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility.

HHS assumes that emergency facilities and health care facilities will provide the notice and obtain consent on behalf of nonparticipating providers, retain records, and notify plans and issuers. HHS estimates that a total of 17,467 health care facilities and emergency departments (including 6,090 hospitals,¹² 475 hospital-affiliated satellite and 270 independent freestanding emergency departments,¹³ 9,280 ambulatory surgical centers,¹⁴ and 1,352 critical access hospitals) will be subject to these requirements. HHS assumes that for hospital-affiliated satellite freestanding emergency departments, the notice and consent will be developed by the parent hospital. Therefore, the burden to develop the notice and consent documents will be incurred by 16,992 emergency facilities and health care facilities. HHS estimates that for each facility it will take a lawyer 1 hour (at an hourly rate of \$143.18) to read and understand the notice and consent forms and make any required and applicable alteration, an administrative assistant half an hour (at an hourly rate of \$38.86) to make any alterations to the provided notice and consent documents and prepare the final documentation, a computer programmer 1 hour (at an hourly rate of \$91.96) to digitize and post on a shared network server or push to networked computers fillable versions of the notice and consent documents, and a computer and information systems manager half an hour (at an hourly rate of \$155.52) to verify accessibility to, and ensure functionality of, the notice and consent documents. HHS estimates the one-time first-year burden, to be incurred in 2021, to make alterations, prepare the final versions, and make accessible to the providers within the facility the notice and consent documentation, for each facility will be approximately 3 hours, with an associated equivalent cost of approximately \$1,332 (including translation costs as discussed in the section on capital costs below). For all 16,992 emergency facilities and health care facilities, HHS estimates a total one-time first-year burden of 50,976 hours, with an associated cost of approximately \$22.6 million.

In order to meet the notice and consent requirements of 45 CFR 149.420 with respect to post-stabilization services, when emergency services are provided by nonparticipating providers or nonparticipating emergency facilities, the provider or facility must provide the participant, beneficiary, or enrollee with a notice and obtain consent to be treated by the nonparticipating emergency facility or nonparticipating provider. HHS estimates there are approximately 5,533 emergency departments (including hospital-affiliated satellite and

¹² American Hospital Association, Fast Facts on U.S. Hospitals, 2021. Available at <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹³ Emergency Medicine Network, 2018 National Emergency Department Inventory – USA. Available at <https://www.emnet-usa.org/research/studies/medi/medi2018/>.

¹⁴ Moriarty, A., Definitive Healthcare, How Many Ambulatory Surgery Centers are in the US?. Blog. April 10, 2019. Available at <https://blog.definitivehc.com/how-many-ascs-are-in-the-us>.

independent freestanding emergency departments)¹⁵ that could be subject to the notice and consent requirements in the 2021 interim final regulations and will incur ongoing annual costs and burdens, beginning in 2022. In 2018, there were approximately 4,146,476 emergency department visits that resulted in hospital admission for patients with individual market or group health coverage.¹⁶ Using this as an estimate of post-stabilization services provided in emergency facilities, and assuming that in 16 percent of cases the patient is treated at a nonparticipating emergency facility or by a nonparticipating provider at a participating facility, HHS estimates that approximately 663,436 individuals will be provided with a notice and consent document for post-stabilization services. HHS anticipates that the notice and consent will be used infrequently for post-stabilization services, so this estimate is an upper bound. HHS estimates it will take a medical secretary 2 hours (at an hourly rate of \$37.50) to customize the required notice and consent documents, generate a list of participating providers, provide and explain the documents to the individual (or authorized representative), answer questions, and obtain the signed consent if the individual agrees, provide the signed documents on paper or, as practicable, electronically, as selected by the individual, and retain the documentation as required by the 2021 interim final regulations. The total burden for providing the notice and consent documents to individuals at all emergency facilities will be 1,326,872 hours with an equivalent cost of approximately \$49.8 million. The total ongoing costs (including the printing and materials costs discussed in the section on capital costs below) for all emergency facilities will be approximately \$49.8 million annually. HHS assumes that nonparticipating providers and nonparticipating emergency facilities will notify the plan or issuer and provide a copy of the signed notice and consent documents along with the claim form electronically at minimal cost.

HHS estimates that each individual that receives notice and consent from an emergency facility will require, on average, 45 minutes (at an hourly rate of \$54.14) to read and understand and sign the required notice and consent documents, with a total cost of approximately \$41. For all 663,436 individuals that could potentially receive the notice and consent documents, HHS estimates a total annual burden of 497,577 hours, with an associated total annual cost of approximately \$26.9 million.

In order to meet the notice and consent requirements of 45 CFR 149.420 with respect to non-emergency services furnished by a nonparticipating provider at a participating health care facility, if an individual schedules an appointment for such items or services at least 72 hours before the date of the appointment, the provider or facility must provide the notice to

¹⁵ Emergency Medicine Network, 2018 National Emergency Department Inventory – USA. Available at <https://www.emnet-usa.org/research/studies/nedi/nedi2018/>.

¹⁶ Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits. Available at <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsEDServlet?measure1=01&characteristic1=14&measure2=&characteristic2=11&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide>.

the individual, or their authorized representative, no later than 72 hours before the date of the appointment. If an individual schedules an appointment for such items or services within 72 hours of the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, on the day that the appointment is made. In the situation where an individual is provided the notice on the same day that the items or services are furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements applies.

HHS estimates there are approximately 16,722 health care facilities that will be subject to the notice requirement and will incur ongoing annual costs and burdens beginning in 2022. Based on 2016 data, HHS estimates that there will be 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures for individuals with group health coverage or individual market coverage¹⁷ and that approximately 16 percent of those visits will involve a nonparticipating provider.¹⁸ This estimate is a lower bound since it is based on the number of postoperative office visits and potentially excludes situations where such visits were not needed or such follow-up was conducted at a different setting. HHS therefore estimates that approximately 1,777,129 individuals could potentially face balance billing and will be provided this notice. With respect to non-emergency services furnished by a nonparticipating provider at a participating health care facility, HHS estimates it will take a medical secretary 1 hour (at an hourly rate of \$37.50) to customize the required notice, generate a list of participating providers, provide the document via email or mail, as selected by the individual, and answer any questions. For all health care facilities, HHS estimates a total annual ongoing annual burden of approximately 1,777,129 hours, with an associated annual cost of approximately \$66.6 million. The total ongoing cost for all health care facilities (including the printing and materials costs discussed in the section on capital costs below) will be approximately \$67.4 million annually.

HHS estimates that each individual that receives the notice will require, on average, 45 minutes (at an hourly rate of \$54.14) to read and understand the required notice, with a total cost of \$41. For all 1,777,129 individuals that could receive the notice document, HHS estimates a total annual burden of 1,332,847 hours, with an associated total annual cost of \$72.2 million. HHS assumes that nonparticipating providers (or participating facilities on behalf of such providers) will notify the plan or issuer and provide a copy of the signed notice and consent documents along with the claim from the participating facility electronically at minimal cost.

¹⁷ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

¹⁸ Estimated based on information provided by KFF. Available at <https://www.kff.org/health-costs/poll-finding/data-note-public-worries-about-and-experience-with-surprise-medical-bills/>.

For all emergency and health care facilities, the total ongoing burden will be 3,104,001 hours annually and the total cost (including printing and materials costs discussed in the section on capital costs below) will be approximately \$117,228,780 annually starting in 2022. For all consumers, the total annual burden to read and understand the notice will be 1,830,424 hours with an equivalent cost of \$99,099,147 starting in 2022.

TABLE 4: One-time and Annual Burden and Cost for Emergency Departments and Facilities Related to Notice and Consent

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost	Total Estimated Translating, Printing and Materials Cost	Total Estimated Cost
2021	16,992	16,992	50,976	\$5,646,951	\$16,992,000	\$22,638,951
2022	17,467	2,440,565	3,104,001	\$116,400,048	\$828,732	\$117,228,780
2023	17,467	2,440,565	3,104,001	\$116,400,048	\$828,732	\$117,228,780
3 Year Average	17,309	1,632,707	2,086,326	\$79,482,349	\$6,216,488	\$85,698,837

TABLE 5: Annual Burden and Cost for Individuals Related to Notice and Consent Starting in 2022

Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost	Total Estimated Cost
2,440,565	2,440,565	1,830,424	\$99,099,147	\$99,099,147

5. ICRs Regarding Provider Disclosure on Patient Protections Against Balance Billing (45 CFR 149.430)

Section 2799B-3 of the PHS Act, as added by the No Surprises Act and codified at 45 CFR 149.430, requires providers and facilities to provide disclosures regarding patient protections against balance billing. Health care providers and facilities are required to publicly post and make the disclosure publicly available through a public website accessible free of charge that is easily accessible, without barriers, including via search engines, and that ensures that the information is accessible to the general public. HHS assumes that providers and facilities will enter into agreements for the facilities to provide the disclosure on behalf of the providers and that the required language and information will be developed, posted within the facility, and posted on a public website by the facility. This will ameliorate the burden and cost for the individual provider. Many facilities and providers will be able to enter into an agreement at minimal cost if they renew their contracts prior to 2022. For each facility whose contracts with providers are not due to be renewed before 2022, the burden to enter

into agreements related to this disclosure will vary based on the number of providers that practice within the facility. HHS estimates that for each facility, on average, it will take a lawyer 2 hours (at an hourly rate of \$143.18) to draft an agreement and an administrative assistant 2 hours (at an hourly rate of \$38.86) to provide electronic copies to all providers to sign. The total burden for all 17,467 facilities will be 69,868 hours with an equivalent cost of approximately \$6,359,385, to be incurred as one-time costs in 2021. HHS is unable to estimate how many providers will incur burden to sign the agreement, but anticipates that the burden to sign each agreement will be minimal. In future years, this agreement can be included in the contract between the facilities and providers at no additional cost.

HHS estimates a total of 17,467 health care facilities (including 475 hospital-affiliated satellite and 270 independent freestanding emergency departments) will incur burden and costs to comply with this provision. HHS assumes that for hospital-affiliated satellite freestanding emergency departments, the disclosure will be developed by the parent hospital. HHS estimates that for each facility, on average, it will take a lawyer 2 hours (at an hourly rate of \$143.18) to read and understand the provided notice and draft any additional, clear, and understandable language as may be needed, an administrative assistant 30 minutes (at an hourly rate of \$38.86) to prepare the final document for distribution and make the information publicly available within the facility, and a computer programmer 1 hour (at an hourly rate of \$91.96) to post the information on a separate or existing webpage, in a searchable manner, and to make the content available in an easily downloadable format. The burden will be higher for facilities in states with state laws or All-Payer Model Agreements, but lower for facilities in states without any state laws. HHS assumes that each facility will post a single page document in at least two prominent locations, such as where individuals schedule care, check-in for appointments, or pay bills. HHS estimates the one-time burden, to be incurred in 2021, to develop, prepare, and post the required disclosure information, for each facility will be approximately 3.5 hours, with an associated cost of approximately \$398. For all facilities, HHS estimates a total one-time burden of 59,472 hours, with an associated cost of approximately \$6.8 million (including materials and printing costs discussed in the section on capital costs below). HHS recognizes that there are some small providers and facilities that do not maintain or provide a publicly available website. Such entities are not required to make a disclosure on a public website. Therefore, HHS considers the estimate to be a high-end estimate.

HHS encourages states to develop language to assist providers and facilities in fulfilling this disclosure requirement with respect to stare law protections. There are currently 33 states that have enacted laws to provide some protection to consumers for surprise billing. Some or all of these states may choose to develop model language. HHS assumes that it will take a lawyer 2 hours (at an hourly rate of \$143.18) and an administrative assistant 1 hour (at an hourly rate of \$38.86) to develop and amend the model language. The total one-time burden, to be incurred in 2021, for each state will be 3 hours with an equivalent cost of

approximately \$325. For all 33 states, HHS estimates the total one-time burden will be 99 hours with an equivalent cost of approximately \$10,732.

In addition to requiring providers and facilities to publicly post and make the required disclosure available through a public website, providers and facilities are required to provide individuals the required disclosure information in a one-page (double sided) notice. The required notice must be provided in-person, through the mail or via email, as selected by the participant, beneficiary, or enrollee no later than the date on which the health care provider or health care facility requests payment from the individual (including requests for copayment made at the time of a visit to the provider or facility), or with respect to individuals from whom the health care facility or health care provider does not request payment, no later than the date on which the health care provider or health care facility submits a claim to the group health plan or health insurance issuer. HHS assumes that, in order to reduce burden and costs, facilities will choose to provide the required disclosure to the individual (or their selected representative) at the time the individual is processed for any visit, upon check-in, or when other standard disclosures are shared with individuals with minimal additional burden. HHS estimates that there will be approximately 39,690,940 emergency department visits¹⁹ and 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures²⁰ for individuals with group health coverage or individual market coverage for a total of 50,797,996 visits. HHS recognizes that the number of notices provided by each facility will vary depending on the number of annual visits and that some facilities could incur higher costs to provide the disclosure while others could incur lower costs. The materials and printing costs for the disclosure is discussed in the section on capital costs below.

TABLE 6: One-time Burden and Costs Related to Agreements between Facilities and Providers

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Cost per Response	Total Annual Burden (Hours)	Total Estimated Cost
2021	17,467	17,467	4	\$364.08	69,868	\$6,359,385

¹⁹ Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits.

²⁰ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>. Estimated based on information provided by KFF. Available at: <https://www.kff.org/health-costs/poll-finding/data-note-public-worries-about-and-experience-with-surprise-medical-bills/>.

TABLE 7: One-time and Annual Burden and Cost for Facilities to Provide Disclosure on Patient Protections Against Balance Billing

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost	Total Estimated Printing and Materials Cost	Total Estimated Cost
2021	17,467	17,467	59,472	\$6,758,568	\$2,965	\$6,761,533
2022	17,467	50,797,996	0	\$0	\$2,539,900	\$2,539,900
2023	17,467	50,797,996	0	\$0	\$2,539,900	\$2,539,900
3 Year Average	17,467	33,871,153	19,824	\$2,252,856	\$1,694,255	\$3,947,111

TABLE 8: One-time Burden and Cost for States to Develop State Specific Language for Facilities to Provide Disclosure on Patient Protections against Balance Billing

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost
2021	33	33	99	\$10,732.26

6. ICRs Regarding Plan and Issuer Disclosure on Patient Protections Against Balance Billing

Plans and issuers are required to make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act apply, information in plain language on the provisions in these sections, and sections 2799B-1 and 2799B-2 of the PHS Act, and other applicable state laws on out-of-network balance billing, and information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing.

The Departments assume that plans and issuers will use the model notice developed by HHS, and that TPAs will develop the notice for self-insured plans. The Departments estimate that on average for each plan or issuer it will take a lawyer 2 hours (at an hourly rate of \$143.18) to read and understand the provided notice and draft any additional, clear, and understandable language as may be needed, an administrative assistant 30 minutes (at an hourly rate of \$38.86) to prepare the final document for distribution and make the information publicly available within the facility, and a computer programmer 1 hour (at an

hourly rate of \$91.96) to post the information on a separate or existing webpage, in a searchable manner, and to make the content available in an easily downloadable format. The total burden for an individual plan or issuer will be 3.5 hours with an equivalent cost of approximately \$398. The burden will be higher for issuers and TPAs in states with applicable state laws or All-Payer Model Agreements, but lower for issuers and TPAs in states without any applicable state laws. The Departments estimate that there are 1,553 issuers and 205 TPAs. The total burden for all issuers and TPAs will be 6,153 hours with an equivalent cost of \$699,245, to be incurred as a one-time cost in 2021. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the burden, or approximately 3,077 hours with an equivalent cost of approximately \$349,622.

Plans and issuers will also include the disclosure along with the explanation of benefits. Under the same assumptions used to estimate the number of disclosures provided by nonparticipating facilities and nonparticipating providers, the Departments estimate that issuers and TPAs will include the disclosure to approximately 39,690,940 individuals who receive services at emergency facilities and 11,107,056 individuals who received non-emergency services at health care facilities, for a total of 50,797,996 disclosures. The Departments assume that for the disclosures sent by mail, it will take an administrative assistant 1 minute (at an hourly rate of \$38.86) to print and enclose the notice with the explanation of benefits. The disclosures sent electronically can be sent at minimal cost. The total burden for all issuers and TPAs is estimated to be 558,778 hours with an equivalent cost of \$21,714,111. The total annual cost to all issuers and TPAs for sending the notices is estimated to be approximately \$23,390,445 (including printing and materials costs discussed in the section on capital costs below) starting in 2022. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the burden, or approximately 279,389 hours, with an equivalent cost of \$10,857,056, and printing and materials cost of \$838,167, for a total annual cost of \$11,695,223 starting in 2022.

TABLE 9: One-time and Annual Burden and Cost for Plans and Issuers to Provide Disclosure on Patient Protections Against Balance Billing

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost	Total Estimated Printing and Materials Cost	Total Estimated Cost
2021	879	879	3,077	\$349,622	0	\$349,622
2022	879	25,398,998	279,389	\$10,857,056	\$838,167	\$11,695,223
2023	879	25,398,998	279,389	\$10,857,056	\$838,167	\$11,695,223
3 year Average	879	16,932,958	187,285	\$7,354,578	\$558,778	\$7,913,356

13. Capital Costs

1. ICRs Regarding Disclosure for Self-Insured Plans Opting-in to State Law (45 CFR 149.30)

HHS estimates that there are approximately 11,956 participants in these plans that will be provided the disclosure. HHS assumes that only printing and material costs are associated with the disclosure requirement, because the notice can be incorporated into existing plan documents. HHS estimates that the disclosure will require one-half of a page, at a cost of \$0.05 per page for printing and materials, and 34 percent of plan documents will be delivered electronically at minimal cost.²¹ Therefore, the cost to deliver 66 percent of these disclosures in print is estimated to be approximately \$197.

TABLE 10: One-time Costs to Provide Disclosure Regarding Opting in to State Law

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Estimated Printing and Materials Cost	Total Estimated Cost
2022	84	11,956	\$197	\$8,981

2. ICRs Regarding Notice and Consent to Waive Balance Billing Protections, Retention of Certain Documents, and Notice to Plan or Issuer (45 CFR 149.410(b)-(e), 45 CFR 149.420(c) - (i))

The burden to develop the notice and consent documents will be incurred by 16,992 emergency facilities and health care facilities. The notice and consent documents must be provided in any of the 15 most common languages in the state, or a geographic region that reasonably reflects the geographic region served by the applicable facility. HHS estimates each facility will incur a cost of approximately \$1,000 (at \$500 per document) to contract with an outside firm to translate the notice and consent documents into the 15 most common languages in the state or a geographic region that reasonably reflects the geographic region served by the applicable facility. The total cost for all facilities, to be incurred in 2021, is estimated to be \$16,992,000.

In order to meet the notice and consent requirements of 45 CFR 149.420 with respect to post-stabilization services, when such services are provided by nonparticipating

²¹ 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>.

providers or nonparticipating emergency facilities, the provider or facility must provide the participant, beneficiary, or enrollee with a notice and obtain consent to be treated by the nonparticipating emergency facility or nonparticipating provider. HHS estimates there are approximately 5,533 emergency departments (including hospital-affiliated satellite and independent freestanding emergency departments)²² that could be subject to the notice and consent requirements in the 2021 interim final regulations and will incur ongoing annual costs and burdens, beginning in 2022. HHS estimates that approximately 663,436 individuals will be provided with a notice and consent document for post-stabilization services. HHS assumes that these documents will be provided directly to each affected individual (or authorized representative) in paper format and will be approximately 4 pages (2 pages printed double-sided) on average. Assuming a cost of \$0.10 (at \$0.05 per page for printing and material cost for each notice and consent document, the total printing and material costs for all notices will be approximately \$66,344, starting in 2022.

In order to meet the notice and consent requirements of 45 CFR 149.420 with respect to non-emergency services furnished by a nonparticipating provider at a participating health care facility, the provider or facility must provide the notice to the individual, or their authorized representative. HHS estimates there are approximately 16,722 health care facilities that will provide approximately 1,777,129 notices. HHS estimates that approximately 66 percent of the notices will be mailed to individuals (34 percent sent electronically) at a cost of \$0.65 (\$0.10 for printing and material cost and \$0.55 postage).²³ Assuming minimal cost for electronic delivery, the total cost of printing and mailing the notice and consent documents will be approximately \$762,388 annually starting in 2022.

The total printing and materials cost for all health care facilities will be approximately \$828,732, starting in 2022. The 3 year average cost for translating, printing, mailing the notice and consent documents is estimated to be \$6,216,488.

TABLE 11: One-time and Annual Costs for Emergency Departments and Facilities Related to Notice and Consent

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Estimated Translating, Printing and Materials Cost
2021	16,992	16,992	\$16,992,000
2022	17,467	2,440,565	\$828,732

²² Emergency Medicine Network, 2018 National Emergency Department Inventory – USA. Available at <https://www.emnet-usa.org/research/studies/nedi/nedi2018/>.

²³ 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>.

2023	17,467	2,440,565	\$828,732
3 Year Average	17,309	1,632,707	\$6,216,488

3. ICRs Regarding Provider Disclosure on Patient Protections Against Balance Billing (45 CFR 149.430)

HHS estimates a total of 17,467 health care facilities will incur burden and costs to comply with the disclosure requirement. HHS assumes that each facility will post a single page document in at least two prominent locations, such as where individuals schedule care, check-in for appointments, or pay bills, and estimates that each facility will incur a printing cost of \$0.10 (at \$0.05 per page for printing and materials) in order to post the required disclosure information prominently at each health care facility. HHS anticipates that 6,090 hospitals will post 6 notices on average, and incur an additional cost of \$0.20 each. The total one-time printing and materials costs to be incurred in 2021 is estimated to be approximately \$2,965.

HHS estimates that health care facilities will provide 50,797,996 disclosures annually starting in 2022. This is a lower bound for the number of patients who will receive the disclosure since HHS lacks comprehensive data on patients who receive services at all health care facilities. In order to provide the required disclosure to individuals, each facility will incur a cost of approximately \$0.05 for printing and materials for each disclosure. HHS assumes that this disclosure will be provided along with other forms and notices usually provided to individuals without incurring significant labor cost. For all facilities, HHS estimates a total annual ongoing annual cost of approximately \$2.5 million, starting in 2022. HHS recognizes that the number of notices provided by each facility will vary depending on the number of annual visits and that some facilities could incur higher costs to provide the disclosure while others could incur lower costs. HHS assumes that all disclosures will be provided in-person; however, HHS acknowledges that some individuals will choose to have this notice provided to them via email, at minimal cost to the facility, and others may choose to receive the disclosure via mail, in which case the facility will incur additional postage costs.

TABLE 12: One-time and Annual Costs for Facilities to Provide Disclosure on Patient Protections Against Balance Billing

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Estimated Printing and Materials Cost
2021	17,467	59,294	\$2,965
2022	17,467	50,797,996	\$2,539,900
2023	17,467	50,797,996	\$2,539,900

3 Year Average	17,467	33,871,153	\$1,694,255
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4. ICRs Regarding Plan and Issuer Disclosure on Patient Protections Against Balance Billing

Plans and issuers will include the disclosure along with the explanation of benefits. Under the same assumptions used to estimate the number of disclosures provided by nonparticipating facilities and nonparticipating providers, the Departments estimate that issuers and TPAs will include the disclosure to approximately 39,690,940 individuals who receive services at emergency facilities and 11,107,056 individuals who received non-emergency services at health care facilities, for a total of 50,797,996 disclosures. The Departments assume that 66 percent of these notices will be provided by mail and the cost of printing is \$0.05 per page. Therefore, the total printing and materials cost for sending 33,526,677 notices by mail will be \$1,676,334 annually, starting in 2022. There will be no additional mailing costs, since the disclosure will be enclosed with the explanation of benefits. As DOL, the Treasury Department, and HHS share jurisdiction, HHS will account for 50 percent of the printing and materials cost, or \$838,167, starting in 2022.

TABLE 13: Annual Cost for Plans and Issuers to Provide Disclosure on Patient Protections Against Balance Billing Starting in 2022

Estimated Number of Respondents	Estimated Number of Responses	Total Estimated Printing and Materials Cost
879	25,398,998	\$838,167

14. Cost to Federal Government

There is no cost to the federal government.

15. Changes to Burden

This is a new collection of information.

Table 14 includes a summary of the burden related to the ICRs and the burden accounted for by each Department.

TABLE 14: Summary of Annual Burden Estimates

Regulation Section	ICR Title	Model Instrument	Percentage of Shared Burden	Shared Burden Hours
45 CFR 149.140(d)	ICRs Regarding Information to be Shared About QPA	No	HHS – 50, DOL – 25 Treasury Department - 25	HHS- 739,158 DOL – 369,579 Treasury Department - 369,579
45 CFR 149.30	ICRs Regarding Disclosure for Self-Insured Plans Opting in to State Law	No	HHS- 100	HHS - 126
45 CFR 149.410(b)-(e), 149.420(c) - (i)	ICRs Regarding Notice and Consent to Waive Balance Billing Protections, Retention of Certain Documents, and Notice to Plan or Issuer	Yes	HHS- 100	HHS - 3,916,750
45 CFR 149.430	ICRs Regarding Provider Disclosure on Patient Protections Against Balance Billing	Yes	HHS – 100	HHS - 89,791
Section 2799A-5(c) of the PHS Act	ICRs Regarding Plan and Issuer Disclosure on Patient Protections Against Balance Billing	Yes	HHS – 50, DOL – 25 Treasury Department - 25	HHS - 187,285 DOL – 93,643 Treasury Department - 93,643

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).

ATTACHMENTS:

- 1. Model Disclosure Notice Regarding Patient Protections Against Surprise Billing**
- 2. Standard Notice and Consent Documents Under the No Surprises Act**