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: 0938-1401)

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 and balance billing 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), and 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 July 13, 2021 interim final rules "Requirements Related to Surprise Billing; Part I" (86 FR 36872, henceforth the July 2021 interim final rules) issued by the Department of Health and Human Services (HHS), Department of Labor (DOL), the Department of the Treasury (collectively, the Departments), and the Office of Personnel Management (OPM) 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 related to patient visits to certain types of participating health care facilities, and services furnished by nonparticipating providers of air ambulance services. The July 2021 interim final rules prohibit nonparticipating providers, emergency facilities, and providers of air ambulance services from balance billing participants, beneficiaries, and enrollees in certain situations unless they satisfy

[1] Pub. L. 116-260.

certain notice and consent requirements; 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 July 2021 interim final rules specify that for emergency services furnished by a nonparticipating emergency facility or provider, and for non-emergency services furnished by nonparticipating providers related to a patient visit to certain types of participating health care facilities, 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 July 2021 interim final rules.

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 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.

On August 26, 2022, the Departments published the final rules "Requirements Related to Surprise Billing" (87 FR 52618, henceforth the August 2022 final rules) adding a definition for the term ''downcode''. The August 2022 final rules require additional information about the QPA that must be provided with an initial payment or notice of denial of payment, without a provider, facility, or provider of air ambulance services having to make a request for this information, in cases in which the plan or issuer has downcoded the billed claim. The August 2022 final rules defined the term ''downcode'' to mean the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower QPA than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

The Departments published proposed rules "Federal Independent Dispute Resolution Process," in October 2023 (henceforth the October 2023 proposed rules). These proposed rules would set forth new requirements relating to the disclosure of information that group health plans and health insurance issuers offering group or individual health insurance coverage must include along with the initial payment or notice of denial of payment for certain items and services subject to the surprise billing protections in the No Surprises Act.

The Centers for Medicare & Medicaid Services (CMS) is requesting Office of Management and Budget (OMB) approval for revisions to the information collections included in this information collection request (ICR). CMS is revising this ICR to (1) include revisions to the information to be shared about the QPA; (2) include an information collection related to

downcoding, which was previously included in a separate ICR currently approved under OMB Control Number [1210-0169], (3) include a proposed information collection requiring group health plans and issuers to disclose the legal business name of the group health plan (if any) or issuer; the legal business name of the plan sponsor (if applicable); and the assigned Federal IDR registration number, and (4) update the burden related to QPA audits.

B. Justification

1. Need and Legal Basis

The July 2021 interim final rules 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 July 2021 interim final rules; (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 August 2022 final rules specify that where a QPA is calculated based on a downcoded service code, in addition to the information already required to be provided with an initial payment or notice of denial of payment under the July 2021 interim final rules at 45 CFR 149.140(d), a plan or issuer must provide, if applicable, a statement that all or a portion of the claim was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if any, and a description of any modifiers that were altered or added; and the amount that would have been the QPA had the service code or modifier not been downcoded.

The October 2023 proposed rules propose to align the timeframes described in the disclosure with the timeframes established in the October 2021 interim final rules, by specifying that days are counted using business days (rather than calendar days), where applicable. The October 2023 proposed rules also propose to require that the statement must also explain that the provider, facility, or provider of air ambulance services must notify the Departments as described under 45 CFR 149.510(b)(1)(i), as applicable, to initiate open negotiation. Additionally, the October 2023 proposed rules propose to amend 45 CFR 149.140 by re-designating paragraph (d)(1)(v) as (d)(1)(vi) and adding a new paragraph (d)(1)(v) requiring plans and issuers to disclose the legal business name of the plan (if any) or issuer; the legal business name of the plan sponsor (if applicable); and the Federal IDR registration number assigned under 45 CFR 149.530, as applicable. The Departments propose to amend regulations at 45 CFR 149.140(d) to specify that plans and issuers must disclose the QPA and certain information about the QPA when the recognized amount (or for air ambulance services, the amount on which cost sharing is based) is the amount billed by the provider, facility, or provider of air ambulance services. The Departments propose to amend the regulations to specify that plans and issuers must, in the case of air ambulance services, disclose the QPA and certain information about the QPA when cost sharing is calculated using the QPA.

The No Surprises Act requires the HHS Secretary to audit no more than 25 group health plans and health insurance issuers offering group or individual health insurance coverage annually, and permits additional audits based on complaints, 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 Secretary of HHS may audit any nonfederal governmental health plan in any state, or any issuer in a state where HHS has jurisdiction, for which a complaint or other information about such health plan or issuer involves compliance with the QPA requirements. In addition, the statute 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 enforcement responsibilities of HHS and the states with respect to oversight of health insurance issuer compliance with the federal insurance market reforms are set forth

in the PHS Act. The July 2021 interim final rules 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 properly determining and applying a QPA. 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 Secretary of HHS 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] The Consolidated Appropriations Act enforcement letters[3] outline which provisions each state is enforcing directly or through a collaborative enforcement agreement and the provisions that CMS is enforcing.

The July 2021 interim final rules 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 July 2021 interim final rules 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 or emergency facility furnishing the emergency services is a participating provider or a participating emergency facility with respect to the items or 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 July 2021 interim final rules further apply surprise billing protections in the case of non-emergency services furnished by

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

[3] CAA enforcement letters outline CMS's understanding of the PHS Act provisions, as extended or added by the CAA, that each state is enforcing either directly or through a collaborative enforcement agreement, and the provisions that CMS is enforcing. These letters also communicate whether the federal independent dispute resolution process and the federal patient-provider dispute resolution process apply in each state, and in what circumstances. Available online at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/CAA.

nonparticipating providers with respect to a visit by a participant, beneficiary, or enrollee at certain types of participating health care facilities unless notice and consent requirements as specified in the July 2021 interim final rules have been met. The requirements related to the notice and consent, applicable exceptions to when consent may be sought, 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 July 2021 interim final rules.

In addition to providing the required notice and consent when permitted, in instances when the provider or facility chooses to do so, 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 July 2021 interim final rules 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 with respect to patient visits to certain types of 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 the QPA provided by plans and issuers to nonparticipating providers, nonparticipating emergency facilities, and nonparticipating providers of air ambulance services will provide transparency regarding how the QPA was determined and promote early communication between parties to a potential payment dispute. The proposed amendments to require plans and issuers to disclose the legal business name of the plan (if any) or issuer; plan sponsor (if applicable); and the assigned Federal IDR registration number would help ensure that payment disputes are directed to the appropriate parties, facilitate more productive open negotiations, and reduce the number of ineligible claims ultimately submitted to the Federal IDR process. Additionally, the required disclosure would help nonparticipating providers, facilities, and providers of air ambulance services look up plans, plan sponsors, and issuers in the IDR registry.

The requirement for plans and issuers to disclose information related to downcoded claims, which was finalized in the August 2022 final rules, may assist nonparticipating providers, facilities, and providers of air ambulance services in their meaningful participation in open negotiation and in the Federal IDR process in all payment disputes that involve qualified items or services subject to downcoding. Specifically, in cases in which the plan or issuer has downcoded the billed claim, this information will ensure that the provider, facility, or provider of air ambulance services has information regarding both the QPA (based on the downcoded service code or modifier) and the amount that would have been the QPA had the service code or modifier not been downcoded in order to ascertain what information will demonstrate that the provider's, facility's, or provider of air ambulance services' offer best represents the value of the item or service and aid the certified IDR entity in selecting an offer that best represents the value of the item or service provided.

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 choose to obtain the services of a nonparticipating provider or facility. Plans and issuers will be provided the information they need in order to determine if cost-sharing

protections apply to specific items and services provided by a nonparticipating provider or emergency facility or if the enrollee provided consent to waive those protections.

3. Use of Information Technology

The documents related to the QPA may be provided electronically by plans and issuers to nonparticipating providers, emergency facilities, and providers of air ambulance services. 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 emergency facilities may also be provided electronically.

4. Duplication of Efforts

There is no duplication of efforts for these information collections.

5. Small Businesses

Health care facilities incurring burden related to these information collections 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 health systems. For hospitals, approximately 18 percent of individual hospitals are estimated to be small entities,[4] 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 $7,250 annually over 3 years.

6. Less Frequent Collection

If this information collection is conducted less frequently, individuals in many cases would not have information regarding the protections against surprise medical bills. Additionally, without the information on whether an individual provided consent to be treated by a nonparticipating provider or emergency facility, plans and issuers would 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, facilities, and providers of air ambulance services would 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). Additionally, without

[4] 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.

knowing the legal business name of the plan (if any) or issuer; and plan sponsor (if applicable); and their IDR registration number, nonparticipating providers, facilities, and providers of air ambulance services would not be able to ensure that payment disputes are directed to the appropriate parties, which in turn could result in less productive open negotiations and increase the number of ineligible claims submitted to the Federal IDR process. Without the requirement to disclose information regarding both the QPA (based on the downcoded service code or modifier) and the amount that would have been the QPA had the service code or modifier not been downcoded, nonparticipating providers, facilities, and providers of air ambulance services would not be able to ascertain what information will demonstrate that the provider's, facility's, or provider of air ambulance services' offer best represents the value of the item or service and thus might result in the certified IDR entity selecting an offer that does not best represents the value of the item or service provided.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A notice will be published in the Federal Register, providing the public with a 60-day period to submit written comments on these information collections.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these information collections.

10. Confidentiality

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

11. Sensitive Questions

These information collections 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 the cost of fringe benefits and other indirect costs) for estimating the burden associated with the information

collections.[5] Table 1 below presents the mean hourly wage, the cost of fringe benefits and other indirect costs, 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 ($/hour)	Cost of Fringe Benefits and Other Indirect Costs ($/hour)	Adjusted Hourly Wage ($/hour)
Administrative Assistants, Except Legal, Medical, and Executive	43-6014	$20.87	$20.87	$41.74
Senior Compliance Officer	13-1041	$37.01	$37.01	$74.02
Business Operations Specialist	13-1000	$40.04	$40.04	$80.08
Project Manager	13-1082	$48.85	$48.85	$97.70
Operations Manager	11-1021	$59.07	$59.07	$118.14
Executive Officer	11-1011	$118.48	$118.48	$236.96
Lawyer	23-1011	$78.74	$78.74	$157.48
All Occupations	00-0000	$29.76	$29.76	$59.52
Computer Programmers	15-1251	$49.42	$49.42	$98.84
Medical Secretaries	43-6013	$19.84	$19.84	$39.68
Computer and Information Systems Managers	11-3021	$83.49	$83.49	$166.98

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

The July 2021 interim final rules require plans and issuers to provide certain information regarding the QPA to nonparticipating providers, or 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 when the out-of-network rate is the QPA, with respect to nonparticipating providers of air ambulance services).

The August 2022 final rules added a definition for the term ‘‘downcode’’ to mean the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower QPA than the service code or modifier billed by the provider,

[5] *See* May 2022 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at https://www.bls.gov/oes/current/oes_nat.htm.

facility, or provider of air ambulance services. The August 2022 final rules require that this additional information about the QPA must be provided with an initial payment or notice of denial of payment, without a provider, facility, or provider of air ambulance services having to make a request for this information, in cases in which the plan or issuer has downcoded the billed claim. The August 2022 final rules further specify that, if a QPA is based on a downcoded service code or modifier, in addition to the information already required to be provided with an initial payment or notice of denial of payment, a plan or issuer must provide a statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if any, and which modifiers were altered, added, or removed, if any; and the amount that would have been the QPA had the service code or modifier not been downcoded.

The Departments assume that third party administrators (TPAs) will provide this information on behalf of self-insured plans. In addition, the Departments assume 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 1,705 entities – 1,500 issuers[6] and 205 TPAs[7] –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.[8] The Departments assume that issuers and TPAs will potentially need to calculate the QPA for approximately two-thirds of the claims involving nonparticipating providers or emergency facilities.

In 2018, there were approximately 39,690,940 emergency department visits for patients with individual market or group health coverage.[9] The Departments estimate that approximately 18 percent of these visits[10] will include services provided by nonparticipating providers or 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 emergency facilities for emergency department visits. In addition, in 2018, there were approximately 4,146,476 emergency

[6] Based on data from MLR annual report for the 2021 MLR reporting year, available at https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.
[7] Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.
[8] The Commonwealth Fund, State Balance Billing Protections. https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.
[9] Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits. https://datatools.ahrq.gov/hcup-fast-stats?count=2&tab=hcupfsis&type=subtab.
[10] 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/.

department visits that resulted in hospital admission for patients with individual market or group health coverage.[11] 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,[12] 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 July 2021 interim final rules for reasons such as unforeseen, urgent medical needs or a 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 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.[13] 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 July 2021 interim final rules 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 $39.68) 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

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[11] Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits. https://datatools.ahrq.gov/hcup-fast-stats?count=2&tab=hcupfsis&type=subtab.

[12] 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/

[13] 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/data/ahcd/namcs_summary/2016_namcs_web_tables.pdf.

certification along with 5,068,512 payments or denial notices, is estimated to be approximately 844,752 hours, with an equivalent cost of approximately $33.5 million. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the total burden, or approximately 422,376 burden hours with an equivalent cost of approximately $16.8 million.

According to the March 2020 Health Insurance Coverage Bulletin (HCCI), in 2019, 216.2 million individuals had employer-sponsored insurance (ESI) or non-ESI private health insurance.[14] In 2017, HCCI estimated that, on average, there were approximately 33.3 air ambulance uses per 100,000 people,[15] and the Government Accountability Office (GAO) estimated that approximately 69 percent of air transports resulted in an out-of-network bill.[16] Therefore, the Departments estimate that issuers and TPAs will be required to provide documentation related to QPAs along with the initial payment or notice of denial of payment documents for approximately 49,676 claims[17] annually from nonparticipating providers of air ambulance services. The Departments estimate that for each issuer or TPA it will take a medical secretary 10 minutes (at an hourly rate of $39.68) to prepare the documentation and attach it to each payment or denial notice or explanation of benefits sent to the nonparticipating provider of air ambulance services. 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 for 49,676 initial payments or denial notices related to air ambulance services, is estimated to be approximately 8,279 hours, with an equivalent cost of approximately $328,524. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the total burden, or approximately 4,140 burden hours with an equivalent cost of approximately $164,262.

The Departments assume that of the approximately 5,118,188 instances in which QPA information is sent to nonparticipating providers, emergency facilities, and providers of air ambulance services 50 percent will result in requests to provide additional information and plans and issuers will be required to send additional information to approximately 2,559,094 providers, facilities, and providers of air ambulance services. The Departments estimate that it will take a medical secretary 15 minutes (at an hourly rate of $39.68) to prepare the document and provide it to the provider, facility, or provider of air ambulance services that requested it. The Departments assume that this information will be delivered electronically

[14] Employee Benefits Security Administration. "Health Insurance Coverage Bulletin." (March 2020). https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2020.pdf.

[15] Hargraves, John and Aaron Bloschichak. "Air Ambulances-10-Year Trends in Costs and Use." Health Care Cost Institute. (2019). https://healthcostinstitute.org/emergency-room/air-ambulances-10-year-trends-in-costs-and-use. In 2017, there were on average, 29.3 helicopter ambulance trips per 100,000 people and 4 plane ambulance trips per 100,000 people (29.3 + 4 = 33.3).

[16] Government Accountability Office. "Air Ambulance: Available Data Show Privately-Insured Patients are at Financial Risk." (2019). https://www.gao.gov/assets/gao-19-292.pdf.

[17] 216,200,000 x 0.000333 x 69% = 49,676 air ambulance service claims.

with minimal additional cost. The total estimated annual burden, for all issuers and TPAs, will be approximately 639,774 hours, with an equivalent cost of approximately $25.4 million. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the total burden, or approximately 319,887 burden hours with an equivalent cost of approximately $12.7 million.

As noted above, the Departments estimate that issuers and TPAs will be required to provide documents related to QPAs along with the initial payment or notice of denial of payment for approximately 5,068,512 claims annually from nonparticipating providers or facilities. Additionally, the Departments estimate that issuers and TPAs will be required to provide these documents for approximately 49,676 claims annually from nonparticipating providers of air ambulance services. As estimated in the July 2021 interim final rules, in the absence of data, the Departments assume that approximately 10 percent, or 511,819, of claims from nonparticipating providers, facilities, and providers of air ambulance services will involve downcoding and that it will take a medical secretary 10 minutes (at an hourly rate of $39.68) to prepare the required documentation and include it with each initial payment or notice of denial of payment sent to the nonparticipating provider, facility, or provider of air ambulance services. 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 downcoded claims information along with payments or denial notices, is estimated to be approximately 85,303 hours, with an equivalent cost of approximately $3.4 million. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the total burden, or approximately 42,652 burden hours with an equivalent cost of approximately $1.7 million.

The total annual burden for all issuers and TPAs for providing the initial and additional information related to QPA, including information related to downcoded claims, with the initial payment or notice of denial of payment to a nonparticipating provider, facility or provider of air ambulance services will be 1,578,108 hours, with an equivalent cost of $62,619,328. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the total burden, or approximately 789,054 burden hours with an equivalent cost of approximately $31,309,664.

TABLE 2: Annual Burden and Cost for Plans and Issuers to Provide Information Related to the QPA to Nonparticipating Providers, Emergency Facilities, and Providers of Air Ambulance Services

	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
Initial QPA Information	853	2,534,256	0.167	426,516	$16,924,143

	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
Information related to downcoding	853	255,909	0.167	42,652	$1,692,414
Additional Information	853	1,279,547	0.25	319,887	$12,693,107
Total	853	4,069,713		789,054	$31,309,664

2. Information to be disclosed with the QPA - (45 CFR 149.140(d))

The October 2023 proposed rules would require plans and issuers to also disclose the following information with the QPA: legal business name of the group health plan (if any) or issuer; the legal business name of the plan sponsor (if applicable); and the assigned Federal IDR registration number. The Departments also propose an amendment to align the language in 26 CFR 54.9816-6T(d)(1)(iv), 29 CFR 2590.716-6(d)(1)(iv), and 45 CFR 149.140(d)(1)(iv) with existing regulatory text by replacing the phrase "amount of total payment" with the term "out-of-network rate," as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30. The Departments further propose to require that the statement also explain that the provider, facility, or provider of air ambulance services must notify the Departments as described under proposed 26 CFR 54.9816-8T(b)(1)(i), 29 CFR 2590.716-8(b)(1)(i), and 45 CFR 149.510(b)(1)(i), as applicable, to initiate open negotiation. The Departments also propose to amend regulations at 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) to specify that plans and issuers must disclose the QPA and certain information about the QPA when the recognized amount (or for air ambulance services, the amount on which cost sharing is based) is the amount billed by the provider, facility, or provider of air ambulance services. the Departments propose to amend the regulations to specify that plans and issuers must, in the case of air ambulance services, disclose the QPA and certain information about the QPA when cost sharing is calculated using the QPA.

The Departments assume that TPAs would provide this information on behalf of self-insured plans. The Departments assume that issuers and TPAs would automate the process of preparing and providing this information to nonparticipating providers, facilities, and providers of air ambulance services and that issuers and TPAs would need to make a one-time change to their IT systems to make changes to the currently required QPA notification to incorporate the proposed information described in the proposed new paragraph (d)(1)(v) and paragraph (d)(1)(iv). The Departments estimate that for each issuer and TPA, on average, it would take a computer programmer 3 hours (at an hourly rate of $98.84) to add fillable fields in order to disclose the legal business name of group health plan (if any) or issuer; the legal business name of the plan sponsor (if applicable); and the assigned Federal IDR registration number; to replace the phrase "amount of total payment" with the term "out-of-network rate" in the statement about initiating open negotiation; and to add information notifying the nonparticipating provider, facility, or provider of air ambulance

services of the proposed requirement to notify the Departments to initiate open negotiation. The Departments estimate that the one-time burden for each plan or issuer, to be incurred in 2024, would be 3 hours on average, with an equivalent cost of approximately $297. The Departments estimate a total one-time burden, for all issuers and TPAs, of 5,115 hours, with an equivalent cost of approximately $505,567. As the Departments share jurisdiction, HHS would account for 50 percent of the total burden, or approximately 2,558 burden hours, with an equivalent cost of approximately $252,783.

TABLE 3: One-Time IT Burden and Cost for Plans and Issuers to Incorporate Information Related to QPA to Nonparticipating Providers, Facilities, and Providers of Air Ambulance Services

Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
853	853	3	2,558	$252,783

In addition, the Departments propose to require plans and issuers to make the same disclosures when the recognized amount (or with respect to air ambulance services, the amount on which cost sharing is based) is the amount billed by the provider, facility, or provider of air ambulance services, and not only when the recognized amount (or with respect to air ambulance services, the amount on which cost sharing is based) is the QPA, as these items and services would also be eligible for the Federal IDR process (provided all other eligibility criteria are satisfied). The Departments anticipate that this is not a common occurrence and therefore would not result in an increase in burden for plans and issuers.

3. QPA Audits (45 CFR 149.140(f))

The July 2021 interim final rules 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 properly determining and applying a QPA. As required under statute, HHS expects to conduct no more than 25 audits annually.

QPA Audit Documentation and Recordkeeping

To comply with the QPA audit, issuers and self-funded non-federal governmental plans (or their TPAs) will provide an initial submission of data as requested in a call letter issued by HHS, and if needed, respond and provide additional documentation and clarification as requested by one or more requests for information, respond to documented findings included in one or more criticisms, and review and respond to the draft final report. All information will be submitted to HHS electronically at minimal cost. In addition, issuers and self-funded non-federal governmental plans (or their TPAs) will participate in bi-weekly meetings with HHS as needed. HHS estimates that, for each issuer and self-funded non-federal

governmental plan (or their TPA), a senior compliance officer will need 10 hours (at an hourly rate of $74.02), a business operations specialist will need 74 hours (at an hourly rate of $80.08), an operations manager will need 10 hours (at an hourly rate of $118.14), a project manager will need 10 hours (at an hourly rate of $97.70), an executive officer will need 6 hours (at an hourly rate of $236.96) and a lawyer will need 10 hours (at an hourly rate of $157.48) on average to document the analyses for all products, keep records, and prepare the documentation for submission to HHS upon request. For each audit, HHS estimates that each issuer or self-funded non-federal governmental plan (or their TPA) will have on average 12 responses to HHS' requests for information or document submission. The total burden for each issuer or self-funded non-federal governmental plans (or their TPAs) per year will be approximately 120 hours, on average, with an equivalent cost of approximately $11,821.

We estimate the total burden for all issuers and self-funded non-federal governmental plans (or their TPAs) will be 3,000 hours with an equivalent cost of approximately $295,527.

TABLE 4: Annual Burden for Issuers and TPAs (on behalf of Self-Insured Non-Federal Governmental Plans) related to QPA Audit Analysis Documentation and Recordkeeping

Number of Respondents	Number of Responses	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost
25	300	3,000	$295,527

Corrective Action Plans as a Result of a QPA Audits

In instances where HHS, upon review of documentation submitted during the QPA audit, determines that the plan is not in compliance with one or more of the QPA requirements specified by the No Surprises Act, the self-funded non-federal governmental plan (or their TPA) or issuer will be directed to undertake actions to correct the areas of non-compliance identified. The self-funded non-federal governmental plan (or their TPA) or issuer will provide documentation to HHS that it has addressed the areas on non-compliance cited within 45 calendar days of receipt of the final report by the self-funded non-federal governmental plan (or their TPA) or issuer, or as extended by HHS. We expect that 18 of the issuers and self-funded non-federal governmental plan (or their TPA) audited will be found to be in violation of one or more QPA requirements and will need to complete corrective actions to come into compliance. HHS estimates that for each such issuer and self-funded non-federal governmental plan (or their TPA), a business operations specialist will need 36 hours (at an hourly rate of $80.08) and an operations manager will need 4 hours (at an hourly rate of $118.14), on average, to prepare and submit documentation demonstrating compliance to HHS. HHS estimates the total burden for each issuer and self-funded non-federal governmental plan (or their TPA) will be 40 hours, with an equivalent

cost of approximately $3,355. For all issuers and self-funded non-federal governmental plans (or their TPAs), HHS estimates a total average annual burden of 720 hours, with an equivalent cost of approximately $60,398.

TABLE 5: Annual Burden for TPAs (on behalf of non-federal governmental health plan) and Issuers related to Corrective Action Plans as a Result of a QPA Audit

Number of Respondents	Number of Responses	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost ($)
18	18	720	$60,398

4. 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 Washington[18] opted in and incurred the one-time burden and cost to include the disclosure in their plan documents in 2022. The ongoing cost to provide this information in future years will be minimal and therefore is not estimated.

5. 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 July 2021 interim final rules, nonparticipating providers and emergency facilities must provide the 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

[18] 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.

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 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 has specified 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 (in instances where the provider or facility chooses to do so), 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 July 2021 interim final rules 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 the 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 with respect to a patient visit 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 with respect to 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,[19] 475 hospital-affiliated satellite and 270 independent freestanding emergency departments,[20] 9,280 ambulatory surgical centers,[21] 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. HHS previously estimated that the one-time burden to develop the notice and consent documents was incurred by 16,992 emergency facilities and health care facilities in 2021. Therefore, HHS is only including ongoing annual costs related to these requirements.

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 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 provider or emergency facility. 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 July 2021 interim final rules and will incur ongoing annual costs and burdens. 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.[23] 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 $39.68) to customize the required notice and consent documents, generate a list of participating providers, provide and explain the documents to the

[19] American Hospital Association, Fast Facts on U.S. Hospitals, 2021. Available at https://www.aha.org/statistics/fast-facts-us-hospitals.
[20] Emergency Medicine Network, 2018 National Emergency Department Inventory – USA. Available at https://www.emnet-usa.org/research/studies/nedi/nedi2018/.
[21] 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.
[22] Emergency Medicine Network, 2018 National Emergency Department Inventory – USA. Available at https://www.emnet-usa.org/research/studies/nedi/nedi2018/.
[23] Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits. Available at https://datatools.ahrq.gov/hcup-fast-stats?count=2&tab=hcupfsis&type=subtab.

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 July 2021 interim final rules. 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 $52.7 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 $52.7 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 $59.52) to read and understand and sign the required notice and consent documents, with a total cost of approximately $45. 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 equivalent total annual cost of approximately $29.6 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 with respect to a patient visit 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 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. 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 coverage[24] and that approximately 16 percent of those visits will involve a

[24] 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.

nonparticipating provider.[25] 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 $39.68) 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 equivalent annual cost of approximately $70.5 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 $71.4 million annually.

HHS estimates that each individual that receives the notice will require, on average, 45 minutes (at an hourly rate of $59.52) to read and understand the required notice, with a total cost of approximately $45. 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 equivalent total annual cost of $79.3 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.

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 $124.1 million annually. For all consumers, the total annual burden to read and understand the notice will be 1,830,424 hours with an equivalent cost of $108.9 million.

TABLE 6: Annual Burden and Cost for Emergency Departments and Facilities Related to Notice and Consent

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
17,467	2,440,565	3,104,001	$123,166,771	$957,752	$124,124,522

[25] 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: Annual Burden and Cost for Individuals Related to Notice and Consent

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	$108,946,827	$108,946,827

6. 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 have already entered into agreements for the facilities to provide the disclosure on behalf of the providers and that the required language and information has been developed, posted within the facility, and posted on a public website by the facility. In future years, this agreement can be included in the contract between the facilities and providers at no additional cost.

HHS previously estimated that in 2021, a total of 17,467 health care facilities (including 475 hospital-affiliated satellite and 270 independent freestanding emergency departments) incurred burden and costs to comply with this provision.

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 have chosen to develop model language and incurred one-time costs in 2021.

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 materials and printing costs for the disclosure is discussed in the section on capital costs below.

7. 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 previously estimated that there were 1,500 issuers and 205 TPAs that incurred one-time burden and costs in 2021 to prepare the disclosure and make the information publicly available.

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 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 $41.74) 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 $23.3 million. The total annual cost to all issuers and TPAs for sending the notices (including printing and materials costs discussed in the section on capital costs below) is estimated to be approximately $25 million annually. 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 $11.7 million, and printing and materials cost of $838,167, for a total annual estimated cost of $12.5 million annually.

TABLE 8: Annual Burden and Cost for Plans and Issuers to Provide Disclosure on Patient Protections Against Balance Billing

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
853	25,398,998	279,389	$11,661,696	$838,167	$12,499,863

13. Capital Costs

1. 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 45 CFR 149.420 with respect to post-stabilization services, when such services are provided by nonparticipating providers or 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 provider. HHS estimates there are approximately 5,533 emergency departments (including hospital-affiliated satellite and independent freestanding emergency departments) that could be subject to the notice and consent requirements in the July 2021 interim final rules and will incur ongoing annual costs and burdens. 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 annually.

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 with respect to a patient visit 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 $0.76 ($0.10 for printing and material cost and $0.66 postage).[26] Assuming minimal cost for electronic delivery, the total cost of printing and mailing the notice and consent documents will be approximately $891,408 annually.

The total annual printing and materials cost for all health care facilities will be approximately $957,752.

TABLE 9: Annual Costs for Emergency Departments and Facilities Related to Notice and Consent

[26] 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.

Estimated Number of Respondents	Estimated Number of Responses	Total Estimated Printing and Materials Cost
17,467	2,440,565	$957,752

2. Provider Disclosure on Patient Protections Against Balance Billing (45 CFR 149.430)

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 visits and 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 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.

HHS estimates that health care facilities will provide 50,797,996 disclosures annually. 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 annually. 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 10: Annual Costs for Facilities to Provide Disclosure on Patient Protections Against Balance Billing

Estimated Number of Respondents	Estimated Number of Responses	Total Estimated Printing and Materials Cost
17,467	50,797,996	$2,539,900

3. 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 providers, the Departments estimate that issuers and TPAs will provide the disclosure to approximately 39,690,940 individuals who receive services at emergency facilities and 11,107,056 individuals who receive 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 $1.7 million annually. 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 annually.

TABLE 11: Annual Cost for Plans and Issuers to Provide Disclosure on Patient Protections Against Balance Billing

Estimated Number of Respondents	Estimated Number of Responses	Total Estimated Printing and Materials Cost
853	25,398,998	$838,167

TABLE 12: Summary of Total Annual Burden Estimates for HHS related to these Information Collection Requests

Regulation Section	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting	Total Labor Cost of Reporting	Printing and Materials Cost	Total Cost
§149.140(d)	853	4,070,565	0.19	791,612	$39.87	$31,562,447	$0.00	$31,562,447
§149.140(f) - Initial Audit	25	300	120.00	3,000	$98.51	$295,527	$0.00	$295,527
§149.140(f) - Corrective Action	18	18	40.00	720	$83.89	$60,398	$0.00	$60,398
§149.410(b)-(e), §149.420(c) - (i) – **Facilities and Providers**	17,467	2,440,565	1.27	3,104,001	$39.68	$123,166,771	$957,752	$124,124,522
§149.410(b)-(e), §149.420(c) - (i) – **Consumers**	2,440,565	2,440,565	0.75	1,830,424	$59.52	$108,946,827	$0.00	$108,946,827
§149.430 – Facilities and Providers	17,467	50,797,996	0	0	$0.00	$0.00	$2,539,900	$2,539,900
Section 2799A-5(c) of the PHS Act	853	25,398,998	0.02	279,389	$41.74	$11,661,696	$838,167	$12,499,863
Total	2,477,229	85,149,007		6,009,146		$275,693,666	$4,335,818	$280,029,484

14. Cost to Federal Government

QPA Audits:

Under the No Surprises Act, HHS is required to conduct no more than 25 QPA audits annually, which focus on payments between health insurance issuers or non-federal governmental health plans (or their TPAs) and health care providers, facilities, and providers of air ambulance services when an NSA-covered claim has occurred. This process is carried out through a combination of federal governmental staff and contractors. The annual cost to the Federal Government, in the form of contracted services, to conduct no more than 25 QPA audits is estimated to be approximately $4.4 million. Additionally, the Federal Government will require an HHS employee[27] at the GS-13 level, step 5 (at an

[27] *See* OPM 2023 General Schedule (GS) Locality Pay Tables, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf. The average salaries for the CMS employees includes the locality pay adjustment for the area of Washington-Baltimore-Arlington.

hourly rate of $60.83) 150 hours per audit to oversee each audit, review the information submitted by the audit entity, participate in audit meetings, and review letters/documents relating to the audit and a GS-14 level, step 5 employee (at an hourly rate of $71.88) 30 hours per audit to review the information submitted by the audit entity and review letters/documents relating to the audit. HHS estimate, that the Federal Government will incur an annual burden of 180 hours, with an equivalent cost of approximately $11,281 per audit. To conduct no more than 25 QPA audits annually, we estimate the Federal Government will incur a total annual burden of 4,500 hours, with an equivalent cost of approximately $282,023.

TABLE 13: Annual Contract and Federal Labor Costs for QPA Audits of Self-Insured Non-Federal Governmental Plans (or their TPAs) and Issuers :

Employee	Hourly Wage	Total Hours Per Audit	Total Number of QPA Audits	Total Estimated Annual Burden per audit (Hours)	Total Estimated Federal Labor Cost ($)
Federal Contract Costs			25		$4,400,000
GS-13, step 5	$60.83	150	25	3,750	$282,113
GS-14, step 5	$71.88	30	25	750	$53,910
Total Employee and contract costs		180	25	4,500	$4,682,023

Preparation of PRA package:
The cost to the Federal government associated with the preparation and release of the updated ICR documents is on a triennial basis and includes the time it takes the employee to complete the PRA process, draft a Federal Register notice regarding the updated ICR, if applicable, and post the documents to CMS.gov.

The analysis and preparation of the PRA package and the subsequent release of documents is performed by HHS employees. HHS estimates that on average it takes an HHS employee at the GS-13 level, step 5 (at an hourly rate of $60.83) 40 hours to perform these activities and the triennial cost to the Federal government will be $2,433.

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 5	$60.83	40	$2,433

15. Changes to Burden

For data collections related to the information to be shared about the QPA, the three-year average burden has increased to approximately 791,611.5 hours from approximately 739,158 hours, a total increase of approximately 52,453.5 hours. While there was a decrease in the number of issuers and TPAs from 879 to 853, the increase in burden is due to the requirements to provide additional information about the QPA to nonparticipating providers, emergency facilities, and providers of air ambulance services and a new one-time IT cost for TPAs and issuers to incorporate additional information with the QPA as proposed in the October 2023 proposed rules. The increase in burden is also a result of the inclusion of the requirement that issuers and TPAs include information regarding downcoded claims (currently approved under OMB Control Number 1210-0169).

For data collections related to QPA audits, the three-year average burden has increased to 3,720 hours from 0 hours, a total increase of 3,720 hours due to an increase in the number of audits from less than 10 to 25.

The one-time burden related to the disclosure for self-insured Plans opting-in to state law has been reduced from approximately 126 hours to zero hours as it was estimated that this one-time burden would be incurred in 2022 and any ongoing costs are minimal and not estimated.

For data collections related to the provider disclosure on patient protections against balance billing, the three-year average burden decreased to zero hours from 89,791 hours, a total reduction of 87,791 hours. This decrease in burden is associated with removal of the one-time burdens related to agreements made between facilities and providers to provide the disclosure on behalf of the providers, the requirements that facilities publicly post and make the disclosure publicly available through a public website, and for states to develop language to assist providers and facilities in fulfilling this disclosure requirement with respect to applicable state law protections.

For the data collection related to notice and consent to waive balance billing protections, the three-year average burden has increased to approximately 4,934,425 hours from 3,916,750 hours, a total increase of approximately 1,017,675 hours. This change in burden is a result of the removal of one-time burden of 50,976 hours, incurred in 2021 by emergency departments and facilities to develop the notice and consent form, and has subsequently been replaced by ongoing costs associated with providing the notice and consent form.

For the data collection-related plan and issuer disclosure on patient protections against balance billing, the three-year average burden has increased to 279,389 hours from approximately 187,285 hours, a total increase of approximately 92,104 hours. This change in burden is a result of the removal of one-time burden of 2,984 hours, incurred in 2021 by plans and issuers to develop the notice, and has subsequently been replaced by ongoing costs associated with providing the notice along with the explanation of benefits.

In aggregate, the change in burden associated with changes in this information collection request is an increase in burden to approximately 6,009,146 hours from approximately 4,933,110 hours, an increase of 1,076,036 hours.

16. Publication/Tabulation Dates

There are no plans to publish the outcomes of the information collections.

17. Expiration Date

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

ATTACHMENTS:

1. **Appendix I: Model Disclosure Notice Regarding Patient Protections Against Surprise Billing**

2. **Appendix II: Standard Notice and Consent Documents Under the No Surprises Act**