

## **Supporting Statement – Part A Transparency in Coverage (CMS- 10715/OMB control number 0938-1372)**

### **A. Background**

The Patient Protection and Affordable Care Act, Pub. L. 111-148, was enacted on March 23, 2010 and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, was enacted on March 30, 2010 (collectively, PPACA). PPACA reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term group health plan includes both insured and self-insured group health plans. PPACA amends the PHS Act by adding section 2715A, providing that non-grandfathered group health plans and issuers offering group or individual coverage shall comply with section 1311(e)(3) of PPACA, which addresses transparency in health coverage and imposes certain reporting and disclosure requirements for health plans seeking certification as qualified health plans (QHP) that may be offered through the exchanges. Specifically, paragraph (A) of section 1311(e)(3) of PPACA requires a plan seeking certification as a QHP to make public nine data elements, including any “other information as determined appropriate by the Secretary of the Department of Health and Human Services (HHS).”<sup>1</sup> A plan or coverage that is not offered through an Exchange is required to submit the information required to the Secretary of HHS and the relevant state’s insurance commissioner and make such information available to the public. Paragraph (C) of section 1311(e)(3) of PPACA requires plans to permit individuals to learn the amount of cost sharing (including deductibles, copayments, and coinsurance) under the individual’s coverage that the individual would be responsible for paying, with respect to the furnishing of a specific item or service by an in-network provider, in a timely manner upon the request of the individual. Paragraph (C) specifies that, at a minimum, such information must be made available to the individual through an internet website and through other means for individuals without access to the internet.

On March 27, 2012, HHS issued a final rule that implemented sections 1311(e)(3)(A)-(C) of PPACA at 45 CFR 155.1040(a)-(c) and §156.220 and created standards for QHP issuers to submit specific information related to transparency in coverage. In the preamble to the 2012 final rule, HHS noted that the standards set forth in that rule are, generally, strictly related to QHPs certified to be offered through an Exchange and not the entire individual and small group market. It was further noted that policies for the entire individual and small and large group markets would continue to be addressed in separate rulemaking issued by HHS, and the Departments of Labor and the Treasury (collectively referred to as “the Departments”). In the

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<sup>1</sup> See section 1311(e)(3)(A)(i) through (viii) of PPACA.

HHS 2020 Notice of Benefit and Payment Parameters (NBPP) proposed rule,<sup>2</sup> HHS sought input on ways to provide consumers with greater transparency with regard to their own health care data, QHPs offered through the Federally-facilitated Exchanges, and the cost of health care services. HHS additionally sought comments on ways to further implement section 1311(e)(3) of PPACA.

On June 24, 2019, President Trump issued Executive Order 13877, “Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First.”<sup>3</sup> Section 3(b) of Executive Order 13877 directs the Secretaries of the Departments to issue an advance notice of proposed rulemaking (ANPRM), consistent with applicable law, soliciting comment on a proposal to require health care providers, health insurance issuers, and self-insured group health plans to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care.

To fulfill the Departments’ responsibilities under Executive Order 13877, as well as to implement legislative mandates under section 1311(e)(3) of PPACA and section 2715A of the PHS Act, on November 27, 2019, the Departments published a Notice of Proposed Rulemaking (NPRM) entitled “Transparency in Coverage” (84 FR 65464) in the Federal Register.

On November 12, 2020, the Departments published the “Transparency in Coverage” final rules (85 FR 72158) in the Federal Register.

The Departments received comments in response to the information collection requirements (ICRs) associated with the NPRM. However, due to revisions to policy proposals in the final rules, and to provide stakeholders a robust opportunity to comment on the ICRs, the Departments are affording the public an additional 60-day comment period.

## **B. Justification**

### **1. Need and Legal Basis**

The Departments published the final rules to promote greater transparency in health care pricing, a critical piece of the Administration’s strategy for reforming health care markets by promoting competition and choice in the health care industry through policies and rules that enable, empower, and incentivize consumers to make informed choices about their health care.

The final rules require the disclosure of health care pricing information, effectuating the Departments’ previously expressed intent to engage in rulemaking to implement section 1311(e)(3) of PPACA pursuant to section 2715A of the PHS Act that establish transparency

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<sup>2</sup> 84 FR 227 (Jan. 24, 2019).

<sup>3</sup> 84 FR 30849 (Jun. 27, 2019). The Executive order was issued on June 24, 2019 and was published in the Federal Register on June 27, 2019.

requirements for non-grandfathered group health plans and health insurance issuers offering group and individual coverage that are not limited to QHPs.

In the private health insurance market, consumers are becoming responsible for an increasing share of their health care costs over time through higher deductibles and shifts from copayments to coinsurance in plan benefit design. Therefore, many consumers' out-of-pocket liability is often directly contingent upon the reimbursement rate their health plan or coverage has negotiated with the in-network provider.

Public availability of pricing information will allow insured and uninsured consumers to have access to health insurance coverage information that can be used to understand health care pricing and potentially dampen the rise in health care spending. With better information, consumers may be able to shop for health care items and services more efficiently, and potentially create more competition and demand for lower prices.

The final rules require non-grandfathered plans and issuers in the individual and group markets to disclose to a participant, beneficiary, enrollee, or an authorized representative on behalf of such individual, consumer-specific estimated cost-sharing liability for covered items and services from a particular provider or providers through an internet-based self-service tool and in paper form upon an individual's request. This disclosure will allow a participant, beneficiary, or enrollee to obtain an accurate estimate and understanding of their cost-sharing liability and to effectively shop for covered items and services based on price. Plans and issuers are required to make such information available for a set of 500 covered items and services, enumerated by the Departments, for plan years (or, in the individual market, policy years) that begin on or after January 1, 2023. Plans and issuers are required to make this information available for all covered items and services for plan years (or, in the individual market, policy years) beginning on or after January 1, 2024.

The final rules also require plans and issuers to publicly disclose:

- applicable in-network provider rates, including negotiated rates, derived amounts and underlying fee schedule rates;
- historical data outlining the different billed charges and allowed amounts a plan or issuer has paid for covered items or services, including prescription drugs, furnished by out-of-network providers; and
- negotiated rates and historical net prices for prescription drugs furnished by in-network providers.

This health pricing information is required to be made public through three machine-readable files, as specified in the In-network Rate File technical implementation guidance, the Allowed Amount File technical implementation guidance, and the Prescription Drug File technical

implementation guidance. All three machine-readable files must be posted publicly on an internet website and updated monthly.

## 2. Information Users

Participants, beneficiaries, and enrollees will have easier access to health care pricing information, through an internet-based self-service tool that includes consumer-specific cost-sharing amounts for items and services covered by their plan or coverage. This information will allow consumers to evaluate options for receiving health care from in-network and out-of-network providers, make cost-conscious health care purchasing decisions, and reduce surprises in relation to their out-of-pocket costs for health care services.

Additionally, all consumers, whether insured or uninsured, will have access to information regarding in-network rates, including negotiated rates, for all covered items and services, data related to historical payments made to out-of-network providers, and data related to negotiated rates and historical net prices for prescription drugs. Although a provider's negotiated rates with plans and issuers do not necessarily reflect the prices providers charge to uninsured consumers, uninsured consumers could use this information to gain an understanding of the payment amounts a particular provider accepts for a service. Uninsured consumers or participants, beneficiaries, or enrollees seeking care from a provider may also use this data to negotiate a price prior to receiving an item or service or negotiate a bill after receiving a service.

State and federal enforcement agencies may be able to use the publicly available information, in conjunction with consumer complaints, to help determine if premium rates are set appropriately. Regulatory bodies may also be able to use the information to evaluate prices and identify unwarranted spending variation. State regulators may also be able to use the information to support their oversight of health insurance markets, including supporting their own state-level transparency efforts such as all-payer claims databases, and gaining further insight into the various payment models.

Employers could leverage this health pricing information to negotiate lower prices for their participants and beneficiaries and make improvements to insurance products, such as moving toward value-based plan designs or broadening or narrowing networks based on consumer shopping habits. Additionally, employers and other purchasers of health care items and services may also be able to use the information to evaluate prices and identify unwarranted spending variation.

Third-party developers will have access to all applicable in-network rates (including negotiated rates), out-of-network allowed amounts, and historical net prices for prescription drugs, by payer, for the first time. Third-party developers can use this information to develop and build innovative price comparison web-based tools that can further encourage consumers to make health care decisions based on cost, among other factors. Researchers will have better

information regarding regional and local health care costs, including in-network negotiated rates and out-of-network amounts, which may lead to a better understanding of price dispersion and economic factors that may result in artificially inflated costs. Increasing the availability of health care pricing information will allow researchers to better understand the impact of specific plan, issuer, and provider characteristics on negotiated rates and out-of-network payments, evaluate and supplement existing models and predictions, and formulate new policies and regulatory improvements to improve competition and lower health care spending.

### 3. Use of Information Technology

Specific information listed in the final rules must be made available through a self-service tool made available by the group health plan or health insurance issuer on an internet website. The same information must also be made available through a mailed paper form. Standards for the paper method of disclosure are provided in the final rules.

Plans and issuers are required to publicly disclose applicable rates, including negotiated rates, with in-network providers; data outlining the different billed charges and allowed amounts a plan or issuer has paid for covered items or services, including prescription drugs, furnished by out-of-network providers; and negotiated rates and historical net prices for prescription drugs furnished by in-network providers. This health pricing information is required to be made public through three machine-readable files.

The final rules define a machine-readable file format as a digital representation of data or information in a file that can be imported or read into a computer system for further processing without human intervention while ensuring no semantic meaning is lost. Examples of machine-readable formats include, but are not limited to, .XML, JSON, and .CSV formats. The preamble to the final rules indicates that the requirements for the machine-readable file(s) will be sufficiently defined and standardized under the Departments' technical implementation guidance. This technical implementation guidance will be available for each of the three machine-readable files through GitHub. GitHub is a website and cloud-based service that helps developers store and manage their code, as well as to track and control changes to their code. The GitHub space offers the Departments the opportunity to collaborate with industry, including regulated entities, and third-party developers to ensure the file format is adapted for reporting of the required public disclosure data for various plan designs and contracting models. The GitHub space is available at: <https://github.com/CMSgov/price-transparency-guide>. In addition to the technical implementation guidance, these ICRs include instruments, identified as Appendices to this supporting statement, which provide the data elements that must be included in each of the three machine-readable files.

#### 4. Duplication of Efforts

A group health plan or health insurance issuer that is required to provide certain disclosures with respect to an individual satisfies the requirement if another party, such as an issuer or third-party administrator (TPA), provides the required disclosures and does so in a specific manner.

#### 5. Small Businesses

Information that plans are required to disclose is generally readily available to group health plans or their TPAs and health insurance issuers, which reduces the burden of compliance. The final rules also permit other parties such as issuers or TPAs to provide the information on behalf of plans. This would allow issuers or TPAs to leverage economies of scale to provide the same service to many small plans or issuers, thus reducing the overall burden of the final rules. Issuers and TPAs may also enter into contracts with other third-party entities, such as clearinghouses, in order to meet the requirements in the final rules, which could allow for the development of economies of scale, and thus further reduce the overall burden associated with the final rules. In addition, while the requirements of the final rules do not apply to providers or small hospitals, providers and small hospitals may experience a loss in revenue as a result of the behavior of price-sensitive consumers and self-insured group health plans, and because smaller health insurance issuers may be unwilling to continue paying higher rates than larger health insurance issuers for the same items and services.

#### 6. Less Frequent Collection

The goal of reducing the cost of health care depends in part on participants, beneficiaries, and enrollees making choices about which health care services to purchase, and from which service provider, based on cost. The availability of real-time, consumer-friendly information through an internet-based self-service tool and health pricing information through the machine-readable files is necessary to provide consumers with meaningful information that allows them to make cost-conscious health care purchasing decisions.

#### 7. Special Circumstances

This information collection is not considered a special circumstance.

#### 8. Federal Register/Outside Consultation

A 60-day notice published in the Federal Register on March 1, 2021 (85 FR 86567).

Comments have been addressed. A 30-day notice published in the Federal Register on October 14, 2021 (86 FR 57151). No additional outside consultation was sought.

## 9. Payments/Gifts to Respondents

There are no payments or gifts associated with this collection.

## 10. Confidentiality

CMS will comply with all Privacy Act and Freedom of Information laws and regulations that apply to this collection.

## 11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

## 12. Burden Estimates (Hours & Wages)

CMS has accounted for its share of the cost and burden related to these ICRs. However, because CMS is submitting these ICRs through the common form process, other Departments and Agencies may account for additional burdens and costs related to these ICRs. In particular, CMS expects the Departments of Labor and the Treasury to adopt their respective burdens related to these ICRs.

### **A. Wage Rate Data**

To derive wage estimates, CMS has chosen to use the Contract Awarded Labor Category (CALC)<sup>4</sup> database tool to derive the hourly rates for the burden and cost estimates in the final rules. The CALC tool was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S. General Services Administration (GSA) & Veterans Administration (VA) contracts. CMS chose to use wages derived from the CALC database because, even though the Bureau of Labor Statistics (BLS)<sup>5</sup> data set is valuable to economists, researchers, and others that would be interested in larger, more macro-trends in parts of the economy, the CALC data set is meant to help market research based on existing government contracts in determining how much a project/product will cost based on the required skill sets needed. The CALC data set factors in the fully-burdened hourly rates (base pay + benefits) into the wages whereas BLS does not. CALC occupations and wages provide the Departments with data that aligns more with, and provides more detail related to, the occupations required for the implementation of the requirements in the final rules.

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<sup>4</sup> CALC information and wage rates are available at: <https://calc.gsa.gov/about/>

<sup>5</sup> May 2018 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at: [https://www.bls.gov/oes/current/oes\\_stru.htm](https://www.bls.gov/oes/current/oes_stru.htm).



**TABLE 1: Hourly Wages Used in Burden Estimates**

<b>CALC Occupation Title</b>	<b>Mean Hourly Wage (\$/hour)</b>
Project Manager/Team Lead	\$153.00
Scrum Master	\$105.00
Technical Architect/Sr. Developer	\$149.00
Application Developer, Senior	\$143.00
Business Analyst	\$120.00
UX Researcher/Service Designer	\$154.00
Designer	\$116.00
DevOps Engineer	\$181.00
Customer Service Representative	\$40.00
Web Database/Application Developer IV	\$152.00
Service Designer/Researcher	\$114.00

At full implementation, each group health plan, health insurance issuer, or TPA will have to disclose consumer-specific estimated cost-sharing information for all covered items or services from a particular provider or providers, as well as allowed amounts for covered items and services from out-of-network providers or any other rate that provides a more accurate estimate of an amount a plan or issuer will pay for the requested out-of-network covered item or service. Plans and issuers are required to make this information available to participants, beneficiaries, enrollees, or their authorized representatives through an internet-based self-service tool and are also required to provide this information in a paper form, upon request. In responding to a paper request, the plan or issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. Both the internet-based self-service tool and the paper form must include a notice with several statements, written in plain language, which includes disclaimers relevant to information provided through the disclosure. These notice statements, which can be provided by using a model notice established by the Departments, are required to include a statement related to the potential for providers to practice balance billing, a statement that the actual charges may differ from the disclosed estimates, a statement that the stated estimate is not a guarantee that benefits will be provided for those items and services, a statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's, beneficiary's, or enrollee's deductible and out-of-pocket maximum, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as

a preventive service if the plan or issuer cannot determine whether the request is for a preventive or non-preventive item or service, and a statement that provides any additional information or disclaimers that the group health plan or health insurance issuer determines are appropriate as long as such information is not in conflict with the disclosure requirements of the final rules.

Additionally, plans and issuers are required to disclose, for all covered items and services, applicable rates with in-network providers, including negotiated rates; historical data outlining the different billed charges and allowed amounts a plan or issuer has paid for covered items or services, including prescription drugs, furnished by out-of-network providers; and negotiated rates and historical net prices for prescription drugs furnished by in-network providers through three machine-readable files a format consistent with implementation guidelines established by the Departments. The files must be posted publicly on an internet website and updated monthly.

## **B. Collections of Information**

### **1. ICRs Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees (45 CFR 147.210(b))**

CMS assumes that fully-insured group health plans will rely on health insurance issuers to develop and maintain the internet-based self-service tool and requested disclosures in paper form. While CMS recognizes that some self-insured plans might independently develop and maintain the internet-based self-service tool, at this time CMS assumes that self-insured group health plans will rely on TPAs (including issuers providing administrative services only and non-issuer TPAs) to develop the required internet-based self-service tool. CMS is of the view that most self-insured plans rely on TPAs for performing most administrative duties, such as enrollment and claims processing. For those self-insured plans that choose to develop their own internet-based self-service tools, CMS assumes that they will incur a similar hour burden and cost as estimated for issuers and TPAs as discussed below. In addition, 45 CFR 147.211(b)(3) of the final rules provides for a special rule to prevent unnecessary duplication of the disclosures with respect to health coverage, which provides that a group health plan may satisfy the disclosure requirements if the issuer offering the coverage is required to provide the information pursuant to a written agreement between the group health plan and the health insurance issuer. Thus, CMS uses health insurance issuers and TPAs as the unit of analysis for the purposes of estimating required changes to information technology (IT) infrastructure and administrative hourly burden and costs. Based on recent data, CMS estimates approximately 877 issuers<sup>6</sup> and 103 TPAs<sup>7</sup> would be affected by this information collection.

<sup>6</sup> 2018 MLR Data Trends.

<sup>7</sup> Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

CMS acknowledges that the costs described in these ICRs may vary depending on the number of lives covered, the number of providers and services incorporated into the internet-based self-service tool, and as a consequence of some plans and issuers already having tools that meet most (if not all) of the requirements of the final rules or that can be easily adapted to meet these requirements. In addition, plans and issuers may be able to license existing online cost estimator tools offered by third-party vendors, obviating the need to establish and maintain their own internet-based self-service tool. CMS assumes that any related vendor licensing fees will be dependent upon complexity, volume, and frequency of use, but assumes that such fees will be lower than an overall initial build and associated maintenance costs. Nonetheless, for purposes of the estimates in these ICRs, CMS assumes that all 980 issuers and TPAs will be affected by the final rules. CMS also developed the following estimates based on the mean average size, by covered lives, of issuers and TPAs.

Issuers and TPAs will incur a one-time cost and hour burden to complete the technical build to implement the requirements of the final rules to establish the internet-based self-service tool and the paper form through which disclosures of cost-sharing information (including required notices) in connection with a covered item or service are required to be made. CMS estimates an administrative burden on health insurance issuers and TPAs to make appropriate changes to IT systems and processes to design, develop, implement, and operate the internet-based self-service tool and to make this information available in paper form, transmitted through the mail. CMS estimates that the one-time cost and burden each health insurance issuer or TPA will incur to complete the one-time technical build; including activities such as planning, assessment, budgeting, contracting, building, systems testing, incorporating any necessary security measures, incorporating disclaimer and model notice language, or development of the notice materials for those that choose to make alterations. CMS assumes that this first year one-time cost and burden will be incurred in 2022 to develop and build the internet-based self-service tool and provide information for the 500 required items and services, and that additional one-time costs and burdens will be incurred in 2023 in order to fully meet the requirements of the final rules.

As mentioned above, CMS acknowledges that a number of issuers and TPAs have previously developed some level of cost estimator tool similar to, and containing some functionality related to, the requirements in the final rules. In order to develop the hourly burden and cost estimates, CMS assumes that all issuers and TPAs will need to develop and build their internet-based self-service tool project from start-up to operational functionality. CMS estimates that for each issuer or TPA, on average, it will take a Project Manager/Team Lead 4,160 hours (at \$153 per hour), a Scrum Master 4,160 hours (at \$105 per hour), a Technical Architect/Sr. Developer 4,160 hours (at \$149 per hour), an Application Developer, Senior 4,160 hours (at \$143 per hour), a Business Analyst 4,160 hours (at \$120 per hour), a UX Researcher/Service Designer 4,160 hours (at \$154 per hour), a Designer 4,160 hours (at \$116 per hour), an DevOps Engineer 4,160 hours (at \$181 per hour), and a Web Database/Application Developer IV (at \$152 per hour) 4,160 hours to complete this task. CMS estimates the total hour burden per issuer or TPA

will be approximately 37,440 hours, with an equivalent cost of approximately \$5,295,680. For all 980 issuers and TPAs, the total first year one-time total hour burden is estimated to be 36,672,480 hours with an equivalent total cost of approximately \$5,187,118,560.

**TABLE 2: Total First Year Estimated One-time Cost and Hour Burden for Internet-based Self-service Tool for All Health Insurance Issuers and TPAs**

<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden Hours Per Respondent</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
980	980	37,440	36,672,480	\$5,187,118,560

In addition to the one-time cost and hour burden estimated above, health insurance issuers and TPAs will incur additional costs in the second year of implementation in order to fully meet the requirements of the final rules to include all items and services into their web tool. CMS estimates that for each health insurance issuer and TPA it will take Project Manager/Team Lead 3,120 hours (at \$153 per hour), a Scrum Master 3,120 hours (at \$105 per hour), a Technical Architect/Sr. Developer 3,120 hours (at \$149 per hour), an Application Developer, Senior 4,160 hours (at \$143 per hour), a Business Analyst 2,080 hours (at \$120 per hour), a UX Researcher/Service Designer 2,080 hours (at \$154 per hour), a Designer 1,560 hours (at \$116 per hour), a Web Database/Application Developer IV 3,120 hours (at \$152 per hour), and a DevOps Engineer 2,080 hours (at \$181 per hour) to perform these tasks. The total second year burden for each issuer or TPA will be 24,440 hours, with an equivalent cost of approximately \$3,466,320. For all 980 health insurance issuers and TPAs, the total second year implementation burden is estimated to be 23,938,980 hours with an equivalent total cost of approximately \$3,305,895,915. CMS considers this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing their internet-based self-service tool.

**Table 3: Estimated Year Two Implementation Cost and Hour Burden for Internet-based Self-Service Tool for All Health Insurance Issuers and TPAs**

<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden Hours Per Respondent</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
980	980	24,440	23,938,980	\$3,305,895,915.48

In addition to the one-time costs and hour burdens estimated above, health insurance issuers and TPAs will incur ongoing annual costs such as those related to ensuring cost estimation accuracy, providing quality assurance, conducting website maintenance and making updates, and enhancing or updating any needed security measures. CMS estimates that for each issuer and TPA, it would take a Project Manager/Team Lead 1,040 hours (at \$153 per hour), a Scrum Master 1,300 hours (at \$105 per hour), an Application Developer, Senior 1,560 hours (at \$143

per hour), a Business Analyst 520 hours (at \$120 per hours), a Designer 1,040 hours (at \$116 per hour), a DevOps Engineer 520 hours (at \$181 per hour), a Web Database/Application Developer IV 1,560 hours (at \$152 per hour), and a UX Researcher/Service Designer 520 hours (at \$154 per hour) to perform these tasks. The total annual burden for each issuer or TPA will be 8,060 hours, with an equivalent cost of approximately \$1,113,060. For all 980 health insurance issuers and TPAs, the total annual maintenance burden is estimated to be 7,894,770 hours with an equivalent total cost of approximately \$1,090,242,270. CMS considers this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing their internet-based self- service tool.

**TABLE 4: Estimated Annual Cost and Hour Burden for Maintenance of Internet-based Self-Service Tool for All Issuers and TPAs**

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
980	980	8,060	7,894,770	\$1,090,242,270

CMS estimates the three-year average annual total burden, for all 980 health insurance issuers and TPAs, to develop, build, and maintain an internet-based consumer self-service tool, will be 422,835,410 hours with an average annual total cost of \$3,194,418,915. CMS recognizes that plans, issuers, and TPAs may be able to license existing internet-based self-service tools offered by vendors, obviating the need to establish, upgrade, and maintain their own internet-based self- service tools, and that vendor licensing fees, dependent upon complexity, volume, and frequency of use, could be lower than the burden and costs estimated here.

**TABLE 5: Estimated Three Year Average Annual Hour Burden and Costs for All Issuers and TPAs to Develop and Maintain the Internet-based Self-Service Tool**

Year	Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
2022	980	980	37,440	36,672,480	\$5,187,118,560.00
2023	980	980	24,440	23,938,980	\$3,305,895,915.48
2024	980	980	8,060	7,894,770	\$1,090,242,270.00
3 year Average	980	980	23,313	22,835,410	\$3,194,418,915.16

In addition to the one-time and annual maintenance costs estimated above, health insurance issuers and TPAs will also incur an annual burden and cost associated with customer service representative training, consumer assistance, and administrative and distribution costs related to the disclosures required in the final rules. CMS estimates that, to understand and navigate

the internet-based self-service tool and be able to provide the appropriate assistance to consumers, each customer service representative will require approximately two hours (at \$40 per hour) of annual consumer assistance training at an associated cost of \$80 per hour. CMS estimates that each issuer and TPA will train, on average, 10 customer service representatives annually, resulting in a total annual hour burden of 20 hours and associated total costs of \$800 per health insurance issuer or TPA. For all 980 issuers and TPAs, the total annual hour burden is estimated to be 19,590 hours with an equivalent total annual cost of approximately \$783,600.

**TABLE 6: Estimated Annual Cost and Hour Burden for All Issuers and TPAs to Train Customer Service Representatives to Provide Assistance to Consumers Related to the Internet-based Self-Service Tool**

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
980	9,795	20	19,590	\$783,600.00

CMS estimates the three-year average annual total burden, for all 980 issuers and TPAs to appropriately train customer service representatives will be 13,060 hours with an average annual total cost of \$522,400.

**TABLE 7: Estimated Three-Year Average Annual Cost and Hour Burden for All Issuers and TPAs to Train Customer Service Representatives to Provide Assistance to Consumers Related to the Internet-based Self-service Tool**

Year	Estimated Number of Issuers and TPAs	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
2022	0	0	0	0	\$0.00
2023	980	9,795	20	19,590	\$783,600.00
2024	980	9,795	20	19,590	\$783,600.00
3 year Average	653	6,530	13	13,060	\$522,400.00

CMS assumes that the greatest proportion of beneficiaries, participants, and enrollees who will request disclosure of cost-sharing information in paper form will do so because they do not have access to the internet. However, CMS acknowledges that some consumers with access to the internet will also contact a group health plan or health insurance issuer or TPA for assistance and may request to receive cost-sharing liability information in paper form.

Recent studies have found that approximately 20 million households do not have an internet subscription<sup>8</sup> and that approximately 19 million Americans (6 percent of the population) lack access to fixed broadband services that meet threshold levels.<sup>9</sup> Additionally, a recent Pew Research Center analysis found that 10 percent of U.S. adults do not use the internet, citing the following major factors: difficulty of use, age, cost of internet services, and lack of computer ownership.<sup>10</sup> Additional research indicates that an increasing number, 17 percent, of individuals and households are now considered “smartphone only” and that 37 percent of U.S. adults mostly use smartphones to access the internet and that many adults are forgoing the use of traditional broadband services.<sup>11</sup> Further research indicates that younger individuals and households, including approximately 93 percent of households with householders aged 15 to 34, are more likely to have smartphones compared to those aged over 65.<sup>12</sup> CMS is of the view that the population most likely to use the internet-based self-service tool will generally consist of younger individuals, who are more comfortable using technology and are more likely to have internet access via broadband or smartphone technologies.

CMS estimates there are 212.3 million<sup>13</sup> beneficiaries, participants, or enrollees enrolled in group health plans or with health insurance issuers required to comply the final rules. On average, it is estimated that each issuer or TPA will annually administer the benefits for 108,379 beneficiaries, participants, or enrollees.

Assuming that 6 percent of covered individuals lack access to fixed broadband service and taking into account that a recent study noted that only 1 to 12 percent of patients that have been

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<sup>8</sup> “2017 American Community Survey Single-Year Estimates.” United States Census Bureau. September 13, 2018. Available at: <https://www.census.gov/newsroom/press-kits/2018/acs-1year.html>.

<sup>9</sup> See Eight Broadband Progress Report. Federal Communications Commission. December 14, 2018. Available at: <https://www.fcc.gov/reports-research/reports/broadband-progress-reports/eighth-broadband-progress-report>. In addition to the estimated 19 million Americans that lack access, they further estimate that in areas where broadband is available approximately 100 million Americans do not subscribe.

<sup>10</sup> See Anderson, M., Perrin, A., Jiang, J., Kumar, M. “10% of Americans don’t use the internet. Who are they?” (Pew Research Center. April 22, 2019. Available at: <https://www.pewresearch.org/fact-tank/2019/04/22/some-americans-dont-use-the-internet-who-are-they/>).

<sup>11</sup> See Anderson, M. “Mobile Technology and Home Broadband 2019.” Pew Research Center. June 13, 2019. Available at <https://www.pewinternet.org/2019/06/13/mobile-technology-and-home-broadband-2019/> (finding that overall 17 percent of Americans are now “smartphone only” internet users, up from 8 percent in 2013. The study also shows that 45 percent of non-broadband users cite their smartphones as a reason for not subscribing to high-speed internet).

<sup>12</sup> See Ryan, C. “Computer and Internet Use in the United States: 2016.” American Community Survey Reports: United States Census Bureau. August 2016 Available at: <https://www.census.gov/content/dam/Census/library/publications/2018/acs/ACS-39.pdf>.

<sup>13</sup> “Health Insurance Coverage in the United States: 2019” (Appendix A). United States Census Bureau/ September 15, 2020. Available at: <https://www2.census.gov/programs-surveys/demo/tables/p60/271/table1.pdf>. The number provided excludes those enrolled in Tricare coverage.



offered internet-based or mobile application-based cost estimator tools use them,<sup>14</sup> CMS estimates that on average 6 percent of beneficiaries will seek customer support (a mid-range percentage of individuals that currently use available cost estimator tools) and that an estimated 1 percent of those participants, beneficiaries, or enrollees will request any pertinent information be disclosed to them in paper form resulting in an estimated 0.06 percent of participants, beneficiaries, or enrollees requesting paper information. CMS estimates that each health insurance issuer or TPA, on average, will require a customer service representative to interact with a beneficiary, participant, or enrollee approximately 65 times per year on matters related to cost-sharing liability disclosures required by the final rules. CMS estimates that each customer service representative would spend, on average, 15 minutes (at \$40 per hour) for each interaction, resulting in a cost of approximately \$10 per interaction. CMS estimates that each issuer or TPA will incur an annual hour burden of 16 hours with an associated equivalent cost of approximately \$650, resulting in a total annual burden of 15,924 hours with an associated cost of approximately \$636,942 for all issuers or TPAs.

**TABLE 8: Estimated Annual Cost and Hour Burden for All Issuers and TPAs to Accept and Fulfill Requests for Mailed Disclosures**

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Labor Cost of Reporting
980	63,694	16	15,924	\$636,942.00

CMS estimates the average 3-year annual total burden, for all 980 issuers and TPAs, will be 42,463 hours with an average annual total cost of \$424,628.

**TABLE 9: Estimated Three-Year Average Annual Cost and Hour Burden for All Issuers and TPAs to Accept and Fulfill Requests for Mailed Disclosures**

Year	Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Labor Cost
2022	0	0	0.0	0	\$0
2023	980	63,694	16	15,924	\$636,942.00
2024	980	63,694	16	15,924	\$636,942.00
3 year Average	653	42,463	11	10,616	\$424,628.00

2. ICRs Regarding Requirements for Public Disclosure of In-network Rates, Historical Allowed Amount Data for Covered Items and Services from Out-of-Network Providers and Prescription Drug Pricing Information under 45 CFR 147.21

<sup>14</sup> See Mehrotra, A., Chernew, M., Sinaiko, A. “Health Policy Report: Promises and Reality of Price Transparency.” April 5, 2018. 14 N. Eng. J. Med. 378. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMhpr1715229>.

As discussed in the previous collection of information, CMS assumes group health plans will rely on health insurance issuers and self-insured plans will rely on health insurance issuers or TPAs to develop and update the three machine-readable files. CMS recognizes that there may be some self-insured plans that wish to individually comply with the final rules and will incur a similar hour burden and cost as described below.

CMS estimates a year one one-time burden and cost to health insurance issuers and TPAs to make appropriate changes to IT systems and processes, to develop, implement and operate the In-network Rate File in order to meet the requirements under the final rules. CMS estimates that each health insurance issuer or TPA, on average, will require a Project Manager/Team Lead 364 hours (at \$153 per hour), a Scrum Master 1,404 hours (at \$105 per hour), a Technical Architect/Sr. Developer 2,080 hours (at \$149 per hour), an Application Developer, Senior 1,716 hours (at \$143 per hour), a Business Analyst 1,404 hours (at \$120 per hour), a Service Designer/Researcher 520 hours (at \$114 per hour) and a DevOps Engineer 260 hours (at \$181 per hour) to complete this task. The total first year burden for each health insurance issuer or TPA will be approximately 7,748 hours, with an equivalent associated cost of approximately

\$1,033,240. For all 980 issuers and TPAs, CMS estimates the total one-time first-year burden will be 7,589,166 hours with an associated cost of approximately \$1,012,058,580. CMS emphasizes that these are upper bound estimates that are meant to be sufficient to cover substantial, complex activities that may be necessary for some plans and issuers to comply with these final rules due to the manner in which their current systems are designed. Such activities may include such significant activity as the design and implementation of databases that will support the production of the In-network Rate Files. CMS also emphasizes that these upper bound estimates are meant to be sufficient to cover the possibility of adding or removing additional data elements to the machine readable files that may be contextual or helping clarify the final rule requirements.

**TABLE 10: Estimated One-Time Year-One Cost and Hour Burden for All Health Insurance Issuers and TPAs for the In-network Rates File**

<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden Hours Per Respondent</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
980	980	7,748	7,589,166	\$1,012,058,580.00

In addition to the year one one-time costs estimated above, health insurance issuers and TPAs will incur an additional year two burden and cost to update the In-network Rate File monthly. CMS estimates that for each month, each issuer or TPA will require a Project Manager/Team Lead 22 hours (at \$153 per hour), a Scrum Master 22 hours (at \$105 per hour), a Technical Architect/Sr. Developer 22 hours (at \$149 per hour), an Application Developer, Senior 22 hours (at \$143 per hour), a Business Analyst 13 hours (at \$120 per hour), and a DevOps Engineer 22 hours (at \$181 per hour) to make the required updates and needed adjustments to the In-network Rate File. CMS estimates that each health insurance issuer or TPA will incur a monthly year two burden of 123 hours with an associated monthly cost of approximately \$17,642 to adjust and update the In-network Rate File. Each health insurance issuer or TPA

will need to update the In-network Rate File 12 times during a given year, resulting in a year two burden of 1,476

hours, with an associated equivalent cost of approximately \$211,704. CMS estimates the total year two burden for all 980 health insurance issuers and TPAs will be 1,445,742 hours, with an associated equivalent cost of approximately \$207,364,068. CMS considers this estimate to be an upper-bound estimate and expects ongoing update costs to decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing the In-network Rate File.

**TABLE 11: Estimated Year-Two Cost and Hour Burden for All Health Insurance Issuers and TPAs for the In-network Rates File**

<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden Hours Per Respondent</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
980	11,754	1,476	1,445,742	\$207,364,068.00

In addition to the one-time year-one and year-two monthly costs estimated above, health insurance issuers and TPAs will incur ongoing monthly burdens and costs to update the In-network Rate File monthly as required by the final rules. CMS estimates that for each issuer or TPA it will require a Project Manager/Team Lead 9 hours (at \$153 per hour) and an Application Developer, Senior 22 hours (at \$143 per hour) to make the required updates to the In-network Rate File. CMS estimates that each health insurance issuer or TPA will incur a monthly burden of 31 hours, with an associated cost of approximately \$4,523 to update the In-network Rate File.

Each health insurance issuer and TPA will need to update the Negotiated Rate File 12 times during a given year, resulting in an ongoing annual hour burden of 372 hours, with an associated equivalent cost of approximately \$54,276. CMS estimates the total annual burden for all 980 issuers and TPAs will be 364,374 hours, with an associated equivalent cost of approximately \$53,163,342. CMS considers this estimate to be an upper-bound estimate and expect ongoing file update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the In-network Rate file.

**TABLE 12: Estimated Annual Ongoing Cost and Burden for All Health Insurance Issuers and TPAs for the In-network Rate File**

<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden Hours Per Respondent</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
980	11,754	372	364,374	\$53,163,342.00

CMS estimates the one-time total year one burden for all health insurance issuers and TPAs will be 7,589,166 hours, with an associated equivalent cost of approximately \$1,012,058,580 to develop and build the In-network Rate File. In year two, CMS estimates the burden and costs

to update and maintain the In-network Rate File for all health insurance issuers and TPAs will be 1,445,742 hours, with an associated equivalent cost of approximately \$207,364,068. In subsequent years, CMS estimates the total annual hour burden to maintain and update the In-network Rate File will be 364,374 hours, with an annual associated equivalent cost of approximately \$53,163,342. CMS estimates the three-year average annual total burden, for all health insurance issuers and TPAs, will be 3,133,094 hours, with an average annual associated equivalent total cost of \$424,195,330.

**TABLE 13: Estimated Three Year Average Annual Hour Burden and Costs for All Health Insurance Issuers and TPAs to Develop and Maintain the In-network Rate File**

Year	Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
2021	980	980	7,748	7,589,166	\$1,012,058,580.00
2022	980	11,754	1,476	1,445,742	\$207,364,068.00
2023	980	11,754	372	364,374	\$53,163,342.00
3 year Average	980	8,163	3,199	3,133,094	\$424,195,330.00

CMS estimates a one-time year one burden and cost to health insurance issuers and TPAs to make appropriate changes to IT systems and processes, to develop, implement, and operate the Allowed Amount File showing the unique out-of-network allowed amounts and billed charges for covered items or services furnished by particular out-of-network providers during the 90- day time period that begins 180 days before the publication date of the file. CMS estimates that each health insurance issuer or TPA will require a Scrum Master 520 hours (at \$105 per hour), a Technical Architect/Sr. Developer 780 hours (at \$149 per hour), an Application Developer, Senior 2,080 hours (at \$143 per hour), a Business Analyst 520 hours (at \$120 per hour), and a DevOps Engineer 260 hours (at \$181 per hour) to complete this task. CMS estimates the total on-time first year burden for each health insurance issuer or TPA will be approximately 4,160 hours, with an equivalent associated cost of approximately \$577,720. For all 980 issuers and TPAs, CMS estimates the total one-time year one burden will be 4,074,720 hours, with an equivalent associated cost of approximately \$565,876,740.

**TABLE 14: Estimated One-Time Year One Cost and Hour Burden for All Issuers and TPAs for the Allowed Amount File**

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
980	980	4,160	4,074,720	\$565,876,740.00

In addition to the one-time year one costs estimated above, health insurance issuers and TPAs will incur additional monthly burdens and costs in year two to update the Allowed Amount File. CMS estimates that, in year two, for each health insurance issuer or TPA it will require a Scrum Master 9 hours (at \$105 per hour), an Application Developer, Senior 22 hours (at \$143 per hour), and a DevOps Engineer 22 hours (at \$181 per hour) to make the required monthly Allowed Amount File updates. CMS estimates that each health insurance issuer or TPA will incur a monthly burden of 53 hours, with an equivalent associated cost of approximately \$8,073 to update the Allowed Amount File. CMS estimates that each health insurance issuer or TPA will need to update and make changes to the Allowed Amount File 12 times during a given year, resulting in a year two annual burden of approximately 636 hours, with an equivalent associated cost of approximately \$96,876. CMS estimates the total monthly burden for all 980 health insurance issuers and TPAs will be 622,962 hours, with an equivalent associated cost of approximately \$94,890,042. CMS considers this estimate to be an upper-bound estimate and expect ongoing Allowed Amount File update costs to decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing the Allowed Amount File.

**TABLE 15: Estimated Year Two Cost and Hour Burden for All Health Insurance Issuers and TPAs for the Allowed Amount File**

<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden Hours Per Respondent</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
980	11,754	636	622,962	\$94,890,042.00

In addition to the one-time year one and monthly year two costs estimated above, issuers and TPAs will incur ongoing annual burdens and costs to update the required Allowed Amount File monthly as required in the final rules. CMS estimates that for each health insurance issuer or TPA it will require a Scrum Master 4 hours (at \$105 per hour), and an Application Developer, Senior 9 hours (at \$143 per hour) to make the required monthly Allowed Amount File updates. CMS estimates that each health insurance issuer or TPA will incur a monthly burden of 13 hours, with an equivalent associated cost of approximately \$1,707 to update the Allowed Amount File. CMS estimates that each issuer and TPA will need to update the Allowed Amount File 12 times during a given year, resulting in an ongoing annual burden of approximately 156 hours, with an equivalent associated cost of approximately \$20,484. CMS estimates the total annual burden for all 980 health insurance issuers and TPAs will be 152,802 hours, with an equivalent associated cost of approximately \$20,064,078. CMS considers this estimate to be an upper-bound estimate and expects ongoing Allowed Amount File update costs to decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing the Allowed Amount File.

**Table 16: Estimated Annual Ongoing Cost and Hour Burden for All Issuers and TPAs for the Allowed Amount File**

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
980	11,754	156	152,802	\$20,064,078.00

CMS estimates the total one-time year one burden for all health insurance issuers and TPAs of 4,074,720 hours, with an equivalent associated cost of approximately \$565,876,740 to develop and build the Allowed Amount File to meet the requirements of the final rules. In year two, CMS estimates the burden and costs to update and maintain the Allowed Amount File for all health insurance issuers and TPAs will be 622,962 hours, with an associated equivalent cost of approximately \$94,890,078. In subsequent years, CMS estimates a total annual burden for all health insurance issuers and TPAs to maintain and update the Allowed Amount File will be 152,802 hours, with an annual equivalent associated cost of approximately \$20,064,078. CMS estimates the three-year average annual total hour burden, for all issuers and TPAs, will be 1,616,828 hours with an average annual total equivalent associated cost of \$226,943,620.

**TABLE 17: Estimated Three Year Average Annual Hour Burden and Costs for All Issuers and TPAs to Develop and Maintain the Allowed Amount File**

Year	Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
2021	980	980	4,160	4,074,720	\$565,876,740.00
2022	980	11,754	636	622,962	\$94,890,042.00
2023	980	11,754	156	152,802	\$20,064,078.00
3 year Average	980	8,162	1,651	1,616,828	\$226,943,620.00

CMS estimates a one-time first-year hour burden and cost to health insurance issuers and TPAs to make appropriate changes to IT systems and processes, to develop, implement and operate the Prescription Drug File in order to meet the requirements in the final rules. CMS estimate that each health insurance issuer or TPA will require a Project Manager/Team Lead 260 hours (at \$153 per hour), a Scrum Master 260 hours (at \$105 per hour), an Application Developer, Senior 520 hours (at \$143 per hour), a Business Analyst 520 hours (at \$120 per hour), and a DevOps Engineer 260 hours (at \$181 per hour) to complete this task. The total first year burden for each health insurance issuer or TPA is estimated to be approximately 1,820 hours, with an equivalent associated cost of approximately \$250,900. For all 980 health insurance issuers and TPAs, CMS estimates the total one-time first year burden will be 1,782,690 hours, with an associated equivalent cost of approximately \$245,756,550. CMS emphasizes that these are upper bound estimates that are meant to be sufficient to cover substantial, complex activities that may be necessary for some plans and issuers to comply

with the final rules due to the manner in which their current systems are designed. Such activities may include such significant activity as the design and implementation of databases that will support the production of the Prescription Drug File.

**TABLE 18: Estimated One-Time Year One Cost and Hour Burden for All Health Insurance Issuers and TPAs for the Prescription Drug File**

<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden Hours Per Respondent</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
980	980	1,820	1,782,690	\$245,756,550.00

In addition to the one-time year one cost and burden estimated above, health insurance issuers and TPAs will incur an additional one-time year two burden and costs to change and update the required Prescription Drug File monthly as required by the final rules. CMS estimates that for each month, for each health insurance issuer or TPA, it will require a Project Manager/Team Lead 22 hours (at \$153 per hour), an Application Developer, Senior 22 hours (at \$143 per hour), a Business Analyst 9 hours (at \$120 per hour), and a DevOps Engineer 22 hours (at \$181 per hour) to make the required updates and needed adjustments to the Prescription Drug File. CMS estimates that each health insurance issuer or TPA will incur a monthly, year two burden of 75 hours, with an associated equivalent monthly cost of approximately \$11,574 to update the Prescription Drug File. Each health insurance issuer or TPA will need to update the Prescription Drug File 12 times during a given year, resulting in a year two burden of 900 hours, with an associated equivalent cost of approximately \$138,888. CMS estimates the total year two burden for all 980 health insurance issuers and TPAs will be 881,550 hours, with an associated equivalent cost of approximately \$136,040,796. CMS considers this estimate to be an upper-bound estimate and expects ongoing update costs to decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing the Prescription Drug File.

**TABLE 19: Estimated Year Two Cost and Hour Burden for All Health Insurance Issuers and TPAs for the Prescription Drug File**

<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden Hours Per Respondent</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
980	11,754	900	881,550	\$136,040,796.00

In addition to the one-time year one and monthly year two costs estimated above, in subsequent years, health insurance issuers and TPAs will incur ongoing monthly burdens and costs to update and maintain the Prescription Drug File on a monthly basis. CMS estimates that for each issuer or TPA it will require a Scrum Master 9 hours (at \$153 per hour) and an Application Developer, Senior 22 hours (at \$143 per hour) to make the required updates to



the Prescription Drug File. CMS estimates that each health insurance issuer or TPA will incur a monthly burden of 31 hours, with an associated cost of approximately \$4,523 to update the Prescription Drug File. Each health insurance issuer or TPA will need to update the Prescription Drug File 12 times during a given year, resulting in an ongoing annual burden of 372 hours, with an associated equivalent cost of approximately \$54,276. CMS estimates the total annual burden for all 980 health insurance issuers and TPAs will be 364,374 hours, with an associated equivalent cost of approximately \$53,163,342. CMS considers this estimate to be an upper-bound estimate and expects ongoing update costs to decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing the Prescription Drug File.

**TABLE 20: Estimated Annual Ongoing Cost and Hour Burden for All Health Insurance Issuers and TPAs for the Prescription Drug File**

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
980	11,754	372	364,374	\$53,163,342.00

CMS estimates the total one-time year one burden for all health insurance issuers and TPAs will be 1,782,690 hours and an associated equivalent cost of approximately \$245,756,550 to develop and build the Prescription Drug File in a machine-readable format. In year two, CMS estimates the burden and costs to update and maintain the Prescription Drug File, on a monthly basis, for all health insurance issuers and TPAs to be 881,550 hours, with an associated equivalent cost of approximately \$136,040,796. In subsequent years, CMS estimates the total annual burden to maintain and update the Prescription Drug File will be 364,374 hours, with an annual associated equivalent cost of approximately \$53,163,342. CMS estimates the three-year average annual total burden, for all health insurance issuers and TPAs, will be 1,009,538 hours with an average annual associated equivalent total cost of \$144,986,896.

**TABLE 21: Estimated Three Year Average Annual Hour Burden and Costs for All Issuers and TPAs to Develop and Maintain the Prescription Drug File**

Year	Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
2021	980	980	1,820	1,782,690	\$245,756,550.00
2022	980	11,754	900	881,550	\$136,040,796.00
2023	980	11,754	372	364,374	\$53,163,342.00
3 year Average	980	8,162	1,031	1,009,538	\$144,986,896.00

**TABLE 22: Estimated Three Year Average for Annual Recordkeeping and Reporting Requirements**

	<b>Number of Respondents</b>	<b>Responses</b>	<b>Burden per Respondent (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Total Estimated Labor Cost</b>
Internet-based Self-Service Tool	980	980	23,313	22,835,410	\$3,194,418,915.16
Customer Service Representatives Training	653	6,530	13	13,060	\$522,400.00
Requests for Mailed Disclosures	653	42,463	11	10,616	\$424,628.00
In-Network Rate File	980	8,163	3,199	3,133,094	\$424,195,330.00
Allowed Amount File	980	8,163	1,651	1,616,828	\$226,943,620.00
Prescription Drug File	980	8,163	1,031	1,009,538	\$144,98,896.00
<b>Total</b>		74,460	29,218	28,618,546	\$3,991,491,789.16

13. Capital Costs

CMS also estimated the cost burden associated with the printing and distribution of the disclosure of pricing information by a non-internet means upon request. These costs are discussed below.

1. ICR Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees (45 CFR 147.211)

CMS assumes that all beneficiaries, participants, or enrollees that contact a customer service representative representing their group health plan, health insurance issuer, or TPA will request non-internet disclosure of the internet-based self-service tool information. Of these, CMS estimates that 54 percent of the requested information will be transmitted via email or facsimile at negligible cost to the health insurance issuer or TPA and that 46 percent will request the information be provided via mail. CMS estimates that, on average, each issuer or TPA will send approximately 33 disclosures via mail annually. Based on these assumptions, CMS estimates that the total number of annual disclosures sent by mail for all health insurance issuers or TPAs will be 29,299.

CMS assumes the average length of the printed disclosure will be approximately nine single-sided pages in length, assuming two pages of information (similar to that provided in an explanation of benefit document) for three providers (for a total of six pages) and an additional three pages related to the required notice, with a printing cost of \$0.05 per page. Therefore, including postage costs of \$0.55 per mailing, CMS estimates that each health insurance issuer or TPA would incur a material and printing costs of \$1.00 (\$0.45 printing plus \$0.55 postage

costs) per mailed request. Based on these assumptions, CMS estimates that each health insurance issuer or TPA will incur an annual printing and mailing cost of approximately \$29.91, resulting in a total annual printing and mailing cost of approximately \$29,299.33 for all issuers and TPAs.

**TABLE 23: Estimated Annual Cost for All Issuers and TPAs to Accept and Fulfill Requests for Mailed Disclosures**

Number of Respondents	Number of Mailings	Printing and Materials Cost	Total Cost
980	29,299	\$29,299.33	\$26,299.33

CMS estimates the three-year average annual total cost burden, for all issuers and TPAs will be printing and material costs of \$19,533 for 19,533 mailings.

**TABLE 24: Estimated Three-Year Average Annual Cost for All Issuers and TPAs to Accept and Fulfill Requests for Mailed Disclosures**

Year	Number of Respondents	Responses	Number of Mailings	Total Printing and Materials Cost
2022	0	0	0	\$0
2023	980	29,299	29,299	\$29,299.33
2024	980	29,299	29,299	\$29,299.33
3 year Average	653	19,533	19,533	\$19,532.89

**14. Cost to Federal Government**

There are no costs to the Federal government associated with this information collection.

**15. Changes to Burden**

This is a new information collection.

**16. Publication/Tabulation Dates**

There are no plans to publish the results of this collection.

**17. Expiration Date**

The expiration date and OMB control number will display on the first page of each instrument (top-right corner).

## Appendices:

1. **Transparency in Coverage Model Notice.**
2. **In-network Rate File Data Elements.**
3. **Allowed Amount File Data Elements.**
4. **Prescription Drug File Data Elements.**