Supporting Statement –Transparency in Coverage
(CMS- 10715/OMB control number 0938-1429)

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, the ACA). The ACA 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. The ACA amended 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 the ACA, 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, subparagraph (A) of section 1311(e)(3) of the ACA 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)."[1] 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. Subparagraph (C) of section 1311(e)(3) of the ACA 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. Subparagraph (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[2] that implemented sections 1311(e)(3)(A)-(C) of the ACA 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

[1] *See* section 1311(e)(3)(A)(i) through (viii) of the ACA.

[2] Patient Protection Act and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 FR 18310 (Mar. 27, 2012) (2012 final rule).

HHS 2020 Notice of Benefit and Payment Parameters (NBPP) proposed rule,[3] 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 the ACA.

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."[4] 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 the ACA 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.

On October [X], 2024, the Departments published the Enhancing Coverage of Preventive Services Under the Affordable Care Act proposed rules (2024 proposed rules). A provision in these proposed rules would amend the Transparency in Coverage final rules implementing section 2715A of the PHS Act and section 1311(e)(3) of the ACA by requiring plans and issuers to provide information related to contraceptive coverage and cost-sharing requirements, including a statement in their internet-based self-service tool explaining that over-the-counter (OTC) contraceptive items are covered without cost sharing and without a prescription.

B. Justification

1. Need and Legal Basis

The Departments published the Transparency in Coverage final rules to promote greater transparency in health care pricing. The Transparency in Coverage final rules require the disclosure of health care pricing information. These rules effectuate the Departments' previously expressed intent to engage in rulemaking to implement section 1311(e)(3) of the ACA and section 2715A of the PHS Act that establish transparency requirements for non-

[3] 84 FR 227 (Jan. 24, 2019).

[4] 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.

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 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 Transparency in Coverage 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 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.[5]

The Transparency in Coverage 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

[5] 45 CFR 147.211.

implementation guidance.[6] All three machine-readable files must be posted publicly on an internet website and updated monthly.[7]

As described in the 2024 proposed rules, the proposed amendments to 45 CFR 147.211, if finalized, would require plans and issuers to make an additional cost-sharing information disclosure to participants, beneficiaries, and enrollees as follows: if a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service through an internet-based self-service tool (or on paper, upon request), the proposed rules would require the self-service tool (or paper disclosure) to include with the information a statement explaining that OTC contraceptive items are covered without cost sharing and without a prescription. This statement would be required to include a phone number and internet link that a participant, beneficiary, or enrollee could use to learn more information about the plan's or policy's contraception coverage. Plans and issuers would be required to make such information available for plan years (or, in the individual market, policy years) that begin on or after January 1, 2026.

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. If finalized, the 2024 proposed rules would increase awareness among participants, beneficiaries, and enrollees that OTC contraceptive items are covered without cost sharing and without a prescription.

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

[6] Technical implementation guidance is published at: https://github.com/CMSgov/price-transparency-guide.

[7] 45 CFR 147.212.

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 Transparency in Coverage 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 Transparency in Coverage final rules. If finalized, the 2024 proposed rules would require the additional cost- sharing information regarding OTC contraceptive items covered without cost sharing and without a prescription to be made available through those methods.

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 Transparency in Coverage 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 Transparency in Coverage 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

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

5. Small Businesses

Information that plans are required to disclose is generally readily available to group health plans or their third-party administrators (TPAs) and health insurance issuers, which reduces the burden of compliance. The Transparency in Coverage 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 Transparency in Coverage 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 Transparency in Coverage final rules, which could allow for the development of economies of scale, and thus further reduce the overall burden associated with the Transparency in Coverage final rules. In addition, while the requirements of the Transparency in Coverage 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

The 2024 proposed rules with requests for comment will be published on October XX 2024. The public solicitation for comments related to these information collections will be open for a period of 60 days.

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

CMS has chosen to use the Contract Awarded Labor Category (CALC)[8] database tool to derive average labor costs for estimating the burden and equivalent costs associated with the information collection requirements (ICRs). The CALC tool was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S.

[8] CALC information and wage rates are available at: https://buy.gsa.gov/pricing/.

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) 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 Transparency in Coverage final rules. Table 1 presents the estimated mean hourly wages, which include both base pay and benefits, used in the burden and equivalent cost estimates.

TABLE 1: Hourly Wages Used in Burden Estimates

CALC Occupation Title	Mean Hourly Wage ($/hour)
Project Manager/Team Lead	$146.15
Scrum Master	$123.95
Application Developer, Senior	$137.23
Business Analyst	$103.16
Designer	$107.10
DevOps Engineer	$118.55
Customer Service Representative	$45.83
Web Database/Application Developer IV	$170.35
IT UI/UX Service Designer IV	$167.58
Training Specialist	$99.95

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, 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 can include any other 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 Transparency in Coverage final rules. In addition, when the notice is provided in connection with a search for cost sharing information for any contraceptive item or service, the plan or issuer must include a statement explaining that OTC contraceptive items are covered without a prescription and without cost sharing, along with a phone number and internet link to where a participant, beneficiary, or enrollee can learn more information about the plan's or policy's contraception coverage as proposed in the 2024 Notice of Proposed Rule Making titled "Enhancing Coverage of Preventive Services under the Affordable Care Act."

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 147.211(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 Transparency in Coverage 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 1,467 issuers[9] and 205 TPAs[10] would be affected by this information collection. It is assumed that those under CMS jurisdiction will take on 50 percent of the total burden, while those under Departments of Labor and the Treasury will each account for 25 percent. Therefore, CMS will account for 50 percent of the total burden, while the Departments of Labor and the Treasury will each account for 25 percent. This means, CMS will account for the burden of approximately 734 issuers and 103 TPAs, for a total of 836 issuers and TPAs under its jurisdiction.

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 consequences of some plans and issuers already having tools that meet most (if not all) of the requirements of the Transparency in Coverage 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 836 issuers and TPAs will be affected by the Transparency in Coverage final rules and the Notice of Proposed Rule Making titled “Enhancing Coverage of Preventive Services under the Affordable Care Act” that proposes a new disclosure requirement when participants, beneficiaries, and enrollees search for cost-sharing information for contraceptive items and services through the internet-based self-service tool or on paper, upon request. 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 Transparency in Coverage 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. For most issuers and TPAs, CMS assumes that this first- year one-time cost and burden to develop and build the internet-based self-service tool, as well as

[9] CMS estimates of the number of health insurance companies and the number of issuers (issuer/State combinations) is based on medical loss ratio reports submitted by issuers for the 2022 reporting year. *See* CMS (2022), “Medical Loss Ratio Data and System Resources,” *available at* https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.

[10] Non-issuer TPAs estimate is based on data derived from the 2016 benefit year reinsurance program contributions.

to provide information for the 500 required items and services, was incurred in 2022. Additionally, CMS anticipated that one-time costs and burdens were incurred in 2023 in order to fully comply with the requirements of the Transparency in Coverage 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 Transparency in Coverage final rules. CMS assumed that all issuers and TPAs would need to develop and build their internet-based self- service tool projects from start-up to operational functionality, which incurred an estimated burden of approximately 36,672,480 hours and an associated cost of $5,187,118,560 in 2022.

In addition to the estimated one-time cost and hour burden incurred by issuers and TPAs in 2022, CMS assumed that issuers and TPAs incurred additional costs in the second year, 2023, to fully comply with the final rule requirements by incorporating all items and services into their web tool, resulting in an estimated burden of approximately 23,938,980 hours and an associated cost of $3,305,895,916.

Furthermore, beyond the estimated one-time costs for 2022 and in 2023, in subsequent years, 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. In subsequent years, CMS estimates that for each issuer and TPA, it will take a Project Manager/Team Lead 1,040 hours (at $146.15 per hour), a Scrum Master 1,300 hours (at 123.95 per hour), an Application Developer, Senior 1,560 hours (at 137.23 per hour), a Business Analyst 520 hours (at 103.16 per hour), a Designer 1,040 hours (at $107.10 per hour), a DevOps Engineer 520 hours (at $118.55 per hour), a Web Database/Application Developer IV 1,560 hours (at 170.35 per hour), and an IT UI/UX Service Designer IV 520 hours (at 167.58 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 1,106,771. For all 836 health insurance issuers and TPAs, the total annual maintenance burden is estimated to be 6,738,160 hours with an equivalent total cost of approximately $925,260,222 as shown in Table 2. 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 2: 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
836	836	8,060	6,738,160	$925,260,222

CMS estimates the ongoing average annual total burden, for all 836 health insurance issuers and TPAs, to develop, build, and maintain an internet-based consumer self-service tool, will be 6,738,160 hours with an average annual total cost of $925,260,222 as shown in Table 3. 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 3: Estimated Ongoing Average Annual Hour Burden and Costs for All Issuers and TPAs to Maintain the Internet-based Self-Service Tool

Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
836	836	8,060	6,738,160	$925,260,222

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 Transparency in Coverage 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 $45.83 per hour) of annual consumer assistance training at an associated cost of approximately $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 approximately $917 per health insurance issuer or TPA. For all 836 issuers and TPAs, the total annual hour burden is estimated to be 19,590 hours with an equivalent total annual cost of approximately $766,278 as shown in Table 4.

TABLE 4: 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
836	8,360	20	16,720	$766,278

CMS estimates the ongoing average annual total burden, for all 836 issuers and TPAs to appropriately train customer service representatives will be 16,720 hours with an average annual total cost of $766,278 as shown in Table 5.

TABLE 5: Estimated Ongoing 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

Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
836	8,360	20	16,720	$766,278

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.

Studies have found that approximately 20 million households do not have an internet subscription[11] and that approximately 19 million Americans (6 percent of the population) lack access to fixed broadband services that meet threshold levels.[12] 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.[13] 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.[14] 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.[15] 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[16] beneficiaries, participants, or enrollees enrolled in group health plans or with health insurance issuers that are required to comply the Transparency in Coverage 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 offered internet-based or mobile application-based cost estimator tools use them,[17] CMS

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[11] "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.

[12] *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.

[13] *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/.

[14] *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).

[15] *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.

[16] "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.

[17] *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.

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 Transparency in Coverage final rules. CMS estimates that each customer service representative would spend on average, 15 minutes (at $45.83 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 $745, resulting in a total annual burden of 13,585 hours with an associated cost of approximately
$622,601 for all issuers or TPAs as shown in Table 6.

TABLE 6: 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
836	54,340	16	13,585	$622,601

CMS estimates the average 3-year annual total burden, for all 836 issuers and TPAs, will be 13,585 hours with an average annual total cost of $542,721 as shown in Table 7.

TABLE 7: Estimated Ongoing Average Annual Cost and Hour Burden for All Issuers and TPAs to Accept and Fulfill Requests for Mailed Disclosures

Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Labor Cost
836	54,340	16	13,585	$622,601

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 147.212

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 Transparency in Coverage final rules and will incur a similar hour burden and cost as described below.

CMS assumed that all issuers and TPAs would need 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, which incurred an estimated burden of approximately 7,589,166 hours and an associated cost of $1,012,058,580 in 2022. In addition to the one-time cost and hour burden estimated in 2022, health insurance issuers and TPAs incurred additional costs in the second year, 2023, to update the In-network Rate File, resulting in an estimated burden of approximately 7,589,166 hours and an associated cost of $1,012,058,580.

CMS assumed that all issuers and TPAs would need to make appropriate changes to IT systems and processes, as well as to develop, implement and operate the In-network Rate File in order to meet the requirements under the Transparency in Coverage final rules, which incurred an estimated burden of approximately 7,589,166 and associated cost of $1,012,058,580 in 2022. CMS emphasized that these were upper bound estimates, intended to account for substantial and complex activities that may be necessary for certain plans and issuers to comply with the Transparency in Coverage final rules (85 FR 72158) due to the manner in which their current systems are designed. Such activities may have included such significant activity as the design and implementation of databases that will support the production of the In-network Rate Files. CMS also emphasized that these upper bound estimates were 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 Transparency in Coverage final rule requirements. In addition to the estimated one-time cost and hour burden incurred by issuers and TPAs in 2022, CMS assumed that health insurance issuers and TPAs incurred an additional burden and cost in year two, 2023, to update the In-network Rate File on a monthly basis, resulting in an estimated burden approximately 1,445,742 hours and an associated cost of $207,364,068. Furthermore, beyond the estimated one-time costs for 2022 and 2023, in subsequent years, health insurance issuers and TPAs will incur ongoing monthly burdens and costs to update the In-network Rate File monthly as required by the Transparency in Coverage final rules (85 FR 72158). CMS estimates that for each issuer or TPA it will require a Project Manager/Team Lead 9 hours (at $146.15 per hour) and an Application Developer, Senior 22 hours (at $137.23 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 $4,334 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 $52,013. CMS estimates the total annual burden for all 836 issuers and TPAs will be 310,992 hours, with an associated equivalent cost of approximately $43,482,801 as shown in Table 8. 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 8: Estimated Annual Cost and Burden for All Health Insurance Issuers and TPAs for the In-network Rate File

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
836	10,032	372	310,992	$43,482,801

CMS estimates the ongoing average annual total burden, for all health insurance issuers and

TPAs to update the In-network Rate File, will be 310,992364 hours, with an average annual associated equivalent total cost of approximately $43,482,801 as shown in Table 9.

TABLE 9: Estimated Ongoing Average Annual Hour Burden and Costs for All Health Insurance Issuers and TPAs to Maintain the In-network Rate File

Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
836	10,032	372	310,992	$43,482,801

CMS assumed that all issuers and TPAs would need to make appropriate changes to IT systems and processes, to develop, implement, and operate the Allowed Amount File in 2022. This file would display 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 estimated these changes incurred a total burden of approximately 4,074,720 hours and an associated cost of $565,876,740 for all issuers and TPAs in 2022. In addition to the estimated one-time cost and hour burden incurred by issuers and TPAs in 2022, CMS assumed that issuers and TPAs incurred additional monthly burdens and costs in the second year, 2023, to update the Allowed Amount File, which amounted approximately 622,962 burden hours and an associated cost of $94,890,042.Furthermore, beyond the estimated one-time costs for 2022 and 2023, in subsequent years, health insurance issuers and TPAs will incur ongoing annual burdens and costs to update the required Allowed Amount File monthly as required in the Transparency in Coverage final rules. CMS estimates that for each health insurance issuer or TPA it will require a Scrum Master 4 hours (at $123.95 per hour), and an Application Developer, Senior 9 hours (at $137.23 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 $1,731 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 $20,770. CMS estimates the total annual burden for all 836 health insurance issuers and TPAs will be 130,416 hours, with an equivalent associated cost of approximately $17,364,088 as shown in Table 10. CMS considered this estimate to be an upper-bound estimate and expected that the ongoing costs for updating Allowed Amount File would decline in succeeding years as health insurance issuers and TPAs gain efficiencies and experience in updating and managing the Allowed Amount File.

TABLE 10: Estimated Annual Ongoing Average 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
836	10,032	156	130,416	$17,364,088

CMS estimates the ongoing average annual total hour burden, for all issuers and TPAs to maintain the required Allowed Amount File, will be 130,416 hours with an average annual total equivalent associated cost of $17,364,088 as shown in Table 11.

TABLE 11: Estimated Ongoing Average Annual Hour Burden and Costs for All Issuers and TPAs to Maintain the Allowed Amount File

Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
836	10,032	156	130416	$17,364,088

CMS assumed that all issuers and TPAs would need 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 Transparency in Coverage final rules, incurring a burden of approximately 1,782,690 hours and an associated cost of $245,756,550 in 2022. In addition to the estimated one-time cost and hour burden incurred by issuers and TPAs in 2022, CMS assumed that issuers and TPAs incurred an additional one-time year two burden of approximately 881,550 hours and an associated cost of $136,040,796 in 2023 to change and update the required Prescription Drug File monthly as required by the Transparency in Coverage final rules. Furthermore, beyond the estimated one-time costs for 2022 and 2023, 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 $123.95 hour) and an Application Developer, Senior 22 hours (at $137.23 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 $4,135 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 $49,615. CMS estimates the total annual burden for all 836 health insurance issuers and TPAs will be 310,992 hours, with an associated equivalent cost of approximately $30,287,210 as shown in Table 12. 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 12: Estimated Annual Ongoing Cost and Hour Burden for All Issuers and TPAs to Maintain the Prescription Drug File

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
836	10,032	372	310,992	$30,287,210

CMS estimates that the ongoing average annual total burden, for all health insurance issuers and TPAs to maintain the Prescription Drug File, will be 310,992 hours with an average annual associated equivalent total cost of $30,287,210 as shown in Table 13.

TABLE 13: Estimated Ongoing Average Annual Hour Burden and Costs for All Issuers and TPAs to Maintain the Prescription Drug File

Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
836	10,032	372	310,992	$30,287,210

3. ICR Regarding Requirements for Contraceptive Disclosure to Participants, Beneficiaries, or Enrollees on the Internet-Based Self-Service Tool (45 CFR 147.211)

CMS proposes in new 45 CFR 147.211(b)(1)(vi) that if a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service using a plan's or issuer's internet-based self-service tool, a plan or issuer must provide a statement explaining the availability of OTC contraceptive items without a prescription and without cost sharing, along with a phone number and internet link to where a participant, beneficiary, or enrollee can learn more information about the plan's or policy's contraception coverage. The Departments propose to require plans and issuers to incorporate this disclosure into their existing self-service tool (or on paper, upon request) for plan years (in the individual market, policy years) beginning on or after January 1, 2026.

CMS assumes that issuers and TPAs have already built self-service tools (first applicable for plan years (or policy years) beginning on or after January 1, 2023) and would only be required to modify their existing tools to incorporate the proposed new contraceptive statement. This statement would explain that OTC contraceptive items are covered without a prescription and without cost sharing and would provide a customer service phone number and internet link for a participant, beneficiary, or enrollee that wishes to speak with a customer service representative or gain additional information about the plan's or policy's contraception coverage.

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 Transparency in Coverage final rules and will incur a similar hour burden and cost as described below.

CMS estimates that for each issuer or TPA, on average, it would take a Project Manager/Team Lead 40 hours (at $146.15 per hour), a Senior Developer/lead 20 hours (at $197.27 per hour), a Designer 25 hours (at $$107.10 per hour), and a Web Database/Application Developer IV 50 hours (at $170.35 per hour) to integrate the contraception statement language into the existing self-service tool, make design changes, and create or update a webpage to provide further details regarding the plan's or policy's contraceptive coverage. The Departments estimate the total hour burden per issuer or TPA would be approximately 135 hours, with an equivalent cost of approximately $20,986 per issuer or TPA. For all 836 issuers and TPAs, the total one-time total hour burden in 2025 is estimated to be 112,860, with an equivalent total cost of approximately $17,544,630 as shown in Table 14.

TABLE 14: Total First Year Estimated One-time Cost and Hour Burden for All Issuers and TPAs Incorporate the New Contraceptive Statement in the Internet-Based Self-service Tool, Make Design Changes, and Develop or Update a Webpage to Provide Further Details Regarding the Plan's or Policy's Contraception Coverage

Number of Respondents	Responses	Burden Hours Per Respondent (hours)	Total Burden Hours	Total Cost
836	836	135	112,860	$ 17,544,630

In addition to the one-time cost and hour burden estimated above, issuers and TPAs would incur ongoing annual costs for website maintenance, programming updates, and updates to the list of contraceptive items and services required to be coded to trigger the statement. CMS estimates that for each issuer and TPA, it would take a Web Database/Application Developer IV 5 hours (at $170.35 per hour) to complete this task. For all 836 issuers and TPAs, the total annual maintenance burden related to the new contraceptive statement would be 4,180 hours with an equivalent total cost of approximately $712,063 as shown in Table 15.

TABLE 15: Estimated Annual Cost and Hour Burden for All Issuers and TPAs for Maintenance of Internet-based Self-Service Tool Related to the New Contraceptive Statement

Number of Respondents	Responses	Burden Hours Per Respondent (hours)	Total Burden Hours	Total Cost
836	836	5	4,180	$ 712,063

Issuers and TPAs would also incur an ongoing annual burden and cost associated with customer service representative training related to the new contraceptive statement. CMS assumes that the introduction of the new contraception statement would not necessitate hiring additional full-time customer service representatives. Instead, CMS expects that issuers and TPAs would utilize their existing customer service representatives for this task. Therefore, CMS estimates that for each issuer and TPA, one Training Specialist would spend 5 hours at a cost of $99.95 per hour to train 5 customer service representatives on how to respond to participants, beneficiaries, and enrollees if they call in because of the new contraception statement, who would also require 5 hours to complete the training at a cost of $45.83 per hour. For all 836 issuers and TPAs, the total annual training hour burden would be 25,080 hours, with an equivalent total annual cost of approximately $1,375,638 as shown in Table 16.

TABLE 16: Estimated Annual Cost and Hour Burden to Train Customer Service Representatives for All Issuers and TPAs to Provide Assistance to Consumers Related to New Contraceptive Statement in the Internet-based Self-Service Tool

Number of Respondents	Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
836	836	30	25,080	$1,375,638

After the training, customer service representatives would be expected to respond to the potential increase in calls resulting from the new contraception statement. CMS estimates that for each issuer and TPA, it would take 5 customer service representatives 5 hours (at $45.83 per hour) to complete this task. For all 836 issuers and TPAs, the total annual cost of responding to these calls would be 20,900 hours, with an equivalent total cost of approximately $957,847 as shown in Table 17.

TABLE 17: Estimated Annual Cost and Hour Burden for All Issuers and TPAs to Respond to Calls regarding the New Contraceptive Statement on the Internet-based Self-Service Tool

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
836	836	25	20,900	$957,847

CMS estimates the three-year average annual total burden, for all health insurance issuers and TPAs to implement and maintain the new contraceptive statement, will be 71,060 hours with an average annual associated equivalent total cost of $7,878,575 as shown in Table 18.

TABLE 18: Estimated Three Year Average Annual Hour Burden and Costs for All Issuers and TPAs to Implement and Maintain the New Contraceptive Statement

Year	Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
Year 1	836	836	135	112,860	$17,544,630
Year 2	836	836	60	50,160	$3,045,548
Year 3	836	836	60	50,160	$3,045,548
3-Year Average	836	836	85	71,060	$7,878,575

TABLE 19: Estimated Ongoing Average for Annual Recordkeeping and Reporting Requirements

	Number of Respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Total Estimated Labor Cost
Internet-based Self-Service Tool	836	836	8,060	6,738,160	$925,260,222
Customer Service Representatives Training	836	8,360	20	16,720	$766,278
Requests for Mailed Disclosures	836	54,340	16	13,585	$622,601
In-Network Rate File	836	10,032	372	310,992	$43,482,801
Allowed Amount File	836	10,032	156	130,416	$17,364,088
Prescription Drug File	836	10,032	372	310,992	$30,287,210
Contraceptive Disclosure	836	836	85	71,060	$7,878,575
Total		94,468	9,081	7,591,925	$1,025,661,774

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 27,588.

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 $0.73 per mailing, CMS estimates that each health insurance issuer or TPA would incur a printing and mailing costs of $1.18 ($0.45 printing plus $0.73 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 $38.94, resulting in a total annual printing and mailing cost of approximately $32,554 for all issuers and TPAs as shown in Table 20.

CMS proposes in new 45 CFR 147.211(b)(1)(vi) that if a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service using a plan's or issuer's internet-based self-service tool (or on paper, upon request), a plan or issuer must provide a statement explaining the availability of OTC contraceptive items without a prescription and without cost sharing, along with a phone number and internet link to where a participant, beneficiary, or enrollee can learn more information about the plan's or policy's contraception coverage. CMS assumes that while participants, beneficiaries, and enrollees will continue to request cost-sharing information on paper in certain circumstances, we assume the proposed additional disclosure would impose negligible additional burden on plans and issuers as the disclosure will likely be no more than one or two sentences and is only required when a participant, beneficiary, or enrollee requests cost-sharing information for covered contraceptive items and services.

TABLE 20: Estimated Annual Cost for All Issuers and TPAs to Accept and Fulfill Requests for Mailed Disclosures

Number of Respondents	Number of Mailings	Total Printing Cost	Total Cost
836	27,588	$12,415	$32,554

CMS estimates the ongoing annual total cost burden, for all issuers and TPAs will be printing and mailing costs of $32,554 for 27,588 mailings as shown in Table 21.

TABLE 21: Estimated Ongoing Average Annual Cost for All Issuers and TPAs to Accept and Fulfill Requests for Mailed Disclosures

Number of Respondents	Responses	Number of Mailings	Total Printing and Mailing Cost
836	27,588	27,588	$32,554

14. Cost to Federal Government

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

15. Changes to Burden

The overall burden has decreased from 28,618,546 to 7,591,925 hours, resulting in a total burden reduction of 21,026,621 hours. Consequently, the associated cost has decreased from
$1,036,852,972 to $28,618,546, resulting in a reduction of $1,008,234,426. Although the introduction of the proposed rule to incorporate the contraceptive disclosure into the existing internet-based self-service tool led to a slight increase in burden, the significant reduction in the overall burden is primarily due to removal of first- and second-year one-time burden for issuers and TPAs to develop and implement their internet-based self-service tool, which were incurred in 2022 and 2023. Additionally, the overall reduction in burden is partially due to the updated count of issuers and TPAs, resulting in a decreased total number of these entities.

In addition to these changes in burden, CMS has updated the CFR citations in this Transparency in Coverage Supporting Statement's ICR section headings to correct errors in

the prior version of the Transparency in Coverage Supporting Statement. The citation in the section heading for the ICRs Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees was updated from 45 CFR 147.210(b) to 45 CFR 147.211(b). The citation in the section heading for 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 was updated from 45 CFR
147.21 to 45 CFR 147.212.

16. Publication/Tabulation Dates

There are no plans to publish the results of this collection as this information collection only requires a third-party disclosure.

17. Expiration Date

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

18. Certification Statement

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

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.**
5. **Internet-based Self-service Tool Model Statement.**