SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995: AFFORDABLE CARE ACT PATIENT PROTECTION NOTICE

This ICR seeks approval of a Revision to an active information collection.

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Patient Protection and Affordable Care Act (the Affordable Care Act or the Act) was enacted on March 23, 2010. Section 2719A of the Public Health Service Act (the PHS Act), as added by the Affordable Care Act, and the Department's final regulations[1] (29 CFR 2590.715-2719A) provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee.

The statute and the 2015 final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer.

The statute and the 2015 final regulations also provide that a group health plan, or a health insurance issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology.

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. The No Surprises Act added section 2799A-7 of the PHS Act, which contains the patient protections regarding choice of health care professional from section 2719A of the PHS

[1] 80 FR 72191.

Act. These provisions mirror those currently applicable under section 2719A of the PHS Act. Accordingly, the 2015 final regulations and 2021 interim final regulations requires such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. Model language is provided in the 2015 final regulations and in the 2021 interim final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

The No Surprises Act, which Congress enacted as part of the Consolidated Appropriations Act, 2021, amended section 2719A of the PHS Act to specify in new subsection (e) that section 2719A shall not apply with respect to plan years beginning on or after January 1, 2022. The No Surprises Act expanded the patient protections related to emergency services to provide additional protections. In addition, the No Surprises Act added section 2799A-7 of the PHS Act, which contains the patient protections regarding choice of health care professional from section 2719A of the PHS Act. These provisions mirror those currently applicable under section 2719A of the PHS Act (minus the emergency services protections). In addition, the patient protections under the No Surprises Act apply generally to all group health plans and health insurance coverage, including grandfathered health plans. The 2021 interim final regulations "Requirements Related to Surprise Billing; Part I" (henceforth 2021 interim final regulations) add a sunset clause to the current patient protection provisions codified in the 2015 final regulations, and re-codify the provisions related to choice of health care professional in a new section.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The notice of right to designate a primary care provider used by health plan sponsors and issuers to notify certain individuals of their right to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration for using information technology to reduce burden.

The regulation does not restrict plans or issuers from using electronic technology to provide either disclosure. The Department of Labor's regulations under 29 C.F.R. § 2520.104b-1(b) provide that, "where certain material, including reports, statements, and documents, is required under Part I of the Act and this part to be furnished either by direct operation of law or an individual request, the plan administrator shall use measures reasonably calculated to ensure actual receipt of the material by plan participants and beneficiaries." Section 29 CFR 2520.104b-1(c) establishes the manner in which disclosures under Title I of ERISA made through electronic media will be deemed to satisfy the requirement of § 2520.104b-1(b). Section 2520-107-1 establishes standards concerning the use of electronic media for maintenance and retention of records. Under these rules, all pension and welfare plans covered under Title I of ERISA may use electronic media to satisfy disclosure and recordkeeping obligations, subject to specific safeguards.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The No Surprises Act, which was enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260). These interim final rules and The No Surprises Act amend and add provisions to existing rules under the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act. However, only the Department of Health and Human Services has jurisdiction over state and local government plans and individual market plans and the Department of Labor oversees ERISA-covered group health plans. Thus, there will be no duplication of effort with HHS.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

All plans regardless of size are required to notify plan participants of their rights. Model notices have been provided to reduce burden. Notices can be part of other plan documents and within the guidelines of the Department's rules provide notices electronically to minimize burden. These notices are a part of the related new ICRs, No Surprise Act, that the Department and HHS are seeking approval for from OIRA.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If this information were conducted less frequently, affected individuals would not be informed of their right to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no special circumstances that require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.5.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if

the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Contemporaneous with this submission, an interim final rule (IFR) was published in the Federal Register on July 13, 2021 (86 FR 36872). The IFR solicits public comment on the paperwork burden of the information collection request. In accordance with 5 CFR 1320.11(c) and 5 CFR 1320.11(e), the public comment period is for 30 days of OMB's 60 days to provide comments on the rule. The IFR also contains a public comment period on the rule that closes September 7, 2021.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts are provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No assurance of confidentiality has been provided.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.

- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**
- **The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**

PHS Act 2719A and the final regulations affect only plans and participants in plans that require participants to designate a primary care physician and are non-grandfathered plans. The Departments assume that this is most likely to happen in Health Maintenance Organization (HMO and Point-of-Service (POS) type arrangements. Therefore, the Department has estimated the number of plans and participants that have HMO- or POS-type coverage that are not grandfathered group health plans. Further, the Department believes that only plans that relinquish their grandfathered status in 2021 and plans that are still grandfathered in 2022 will become subject to this notice requirement for the first time and incur the one-time costs to prepare the notice. In subsequent years, this notice would remain unchanged and its costs are factored into the burden estimates associated with the Summary Plan Description information collection request (OMB Control Number 1210-0039).

The Department estimates that there are 2.5 million ERISA-covered plans. Data obtained from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 16 percent of firms offering health benefits offer at least one grandfathered health plans. The Department estimates that five percent of plans will relinquish their grandfathered status in 2021. The data from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits also finds that 11 percent of plans have an HMO option and that 31 percent of plans offer a POS option. Thus, the Department estimates that 8,481 plans will lose grandfathered status in 2021 and incur the one-time cost to prepare and incorporate this notice in their existing plan document.[2] In 2022, the remaining 161,148 such grandfathered plans will be subject to this notice requirement.[3] There will be no additional costs in 2023 to prepare the notice, since all plans and issuers will have incurred the cost by 2022.

While not all HMO and POS options require the designation of a primary care physician or a prior authorization or referral before a woman can visit an OB/GYN, the Department is unable to estimate this number. Therefore, these estimates should be considered an overestimate of the number of affected entities.

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2 2.5 million ERISA-covered plans x 16% grandfathered plans x 5% newly non-grandfathered plans x (11% HMOs + 31% POSs) = 8,481 affected plans.

3 2.5 million ERISA-covered plans x 16% grandfathered plans x (100% minus 5% newly non-grandfathered plans) x (11% HMOs + 31% POSs) = 161,148 affected plans.

The 2015 final regulations require that a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is more restrictive than the copayment or coinsurance requirement that would apply if the services were provided in network. If State law prohibits balance billing, or a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, the a plan or issuer must provide an enrollee or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to amounts balanced billed in order to prevent inadvertent payment by an enrollee or beneficiary. This information should already be routinely included in the Explanation of Benefit documents sent by plans and issuers to enrollees and beneficiaries. Therefore, in accordance with the implementing regulations of the Paperwork Reduction Act at 5 CFR 1320.3(b)(2), we believe this is a usual and customary business practice. Plans and issues routinely provide enrollees and beneficiaries with the Explanation of Benefit documents. Plans and issuers will no longer be required to provide this notice for plan years beginning on or after January 1, 2022.

Each of the plans will require a compensation and benefits manager to spend 10 minutes individualizing the model notice to fit the plan's specifications at an hourly rate of $134.21.[4] In 2021, this results in 1,414 hours of burden at an equivalent cost of $189,716. In 2022, this results in 26,858 hours of burden at an equivalent cost of $3,604,602.

Each plan will also require clerical staff to spend 5 minutes adding the notice to the plan's documents at an hourly rate of $55.14. In 2021, this results in approximately 707 hours of burden at an equivalent cost of $38,972. In 2022, this results in 13,429 hours of burden at an equivalent cost of $740,473.

In 2021, the total burden associated with this ICR is 2,120 hours at an equivalent cost of $228,688. In 2022, the total burden associated with this ICR is 40,287 hours at an equivalent cost of $4,345,075. The Department shares this burden equally with the Department of the Treasury. Therefore, the three-year average prorated share of the burden for DOL is approximately 7,068 hours at an equivalent cost of $762,294.

Estimated Annualized Respondent Cost and Hour Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden (Hours)	Total Burden (Hours)	Hourly Wage Rate	Total Burden Cost
Compensation and benefits manager	8,481	1	8,481	10/60	1,414	$134.21	$189,716

4 For more information on how the Department estimates labor costs see: https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf

draft notice (2021)							
Clerical staff insert notice into existing documentation (2021)	8,481	1	8,481	5/60	707	$55.14	$38,972
Compensation and benefits manager draft notice (2022)	161,148	1	161,148	10/60	26,858	$134.21	$3,604,602
Clerical staff insert notice into existing documentation (2022)	161,148	1	161,148	5/60	13,429	$55.14	$740,473
Total (3-year average)*	56,543		256,262		7,068	-	$762,294

* Note: The Department estimates that there are 8,481 respondents in 2021, 161,148 respondents in 2022, and zero respondents in 2023. Thus, the three-year average number of respondents is 56,543.[5] The Department estimates that there are 38,439 responses in 2021, 730,246 responses in 2022, and 0 and responses in 2023.[6] Thus, the three-year average number of responses is 256,262.

13. Provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12.)

- **The cost estimate should be split into two components: (a) a total capital and start up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of service component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of**

5 2021: 2.5 million ERISA-covered plans x 16% grandfathered plans x 5% newly non-grandfathered plans x (11% HMOs + 31% POSs) = 8,481 affected plans; 2022: 2.5 million ERISA-covered plans x 16% grandfathered plans x (100% minus 5% newly non-grandfathered plans) x (11% HMOs + 31% POSs) = 161,148 affected plans; 2023: There will be no additional costs in 2023 to prepare the notice, since all plans and issuers will have incurred the cost by 2022.

6 2021: 62.6 million ERISA-covered policyholders x 14% of covered employees in grandfathered plans x 5% newly non-grandfathered plans x (13% in HMOs + 8% in POSs) *41.8% = 38,439 notices; 2022: 62.6 million ERISA-covered policyholders x 14% of covered employees in grandfathered plans x (100% minus 5% newly non-grandfathered plans) x (13% in HMOs + 8% in POSs) *41.8% = 730,346 notices; 2023: There will be no additional costs in 2023 to prepare the notice, since all plans and issuers will have incurred the cost by 2022.

purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the interim final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Departments estimate that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 58.2 percent of the notices will be delivered electronically.[7]

The Department estimates that there are 62.6 million ERISA-covered policyholders. Data obtained from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 14 percent of covered workers are enrolled in a grandfathered plan. As stated in question 12, the Department estimates that 5 percent of plans would relinquish their grandfathered status annually in 2021. The data from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits also finds that 13 percent of covered workers have an HMO option and that 8 percent of covered workers have a POS option. The Department estimates that plans will produce 38,439 notices in 2021, 730,346 notices in 2022, and zero notices in 2023.[8] This results in a cost burden of approximately $961 in 2021, $18,259 in 2022, and $0 in 2023.[9] The Department shares

7 According to data from the National Telecommunications and Information Agency (NTIA), 40.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure that are automatically enrolled (for a total of 33.6 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 33.6 percent who receive electronic disclosure at work with the 24.7 percent who receive electronic disclosure outside of work produces a total of 58.2 percent who will receive electronic disclosure overall.

8 2021: 62.6 million ERISA-covered policyholders x 14% of covered employees in grandfathered plans x 5% newly non-grandfathered plans x (13% in HMOs + 8% in POSs) *41.8% = 38,439 notices; 2022: 62.6 million ERISA-covered policyholders x 14% of covered employees in grandfathered plans x (100% minus 5% newly non-grandfathered plans) x (13% in HMOs + 8% in POSs) *41.8% = 730,346 notices

9 2021: $0.05 per page*1/2 pages per notice * 38,439 notices = $961; 2022: $0.05 per page*1/2 pages per notice *

this burden equally with the Department of the Treasury. Therefore, DOL's three-year average share of the burden is approximately $3,203.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

There are no costs to the Federal government.

15. Explain the reasons for any program changes or adjustments reporting in Items 13 or 14.

The No Surprises Act added section 2799A-7 of the PHS Act, which contains the patient protections regarding choice of health care professional from section 2719A of the PHS Act. The patient protections under the No Surprises Act apply generally to all group health plans and health insurance coverage, including grandfathered health plans. The Department believes that only plans that relinquish their grandfathered status in 2021 and plans that are still grandfathered in 2022 will become subject to this notice requirement for the first time and incur the one-time costs to prepare the notice.

Adjustments to the burden estimates also result from updated estimates on the number of plans and policyholders affected by the regulations, an increase in the share of notices assumed to be transmitted electronically, and increases in wage rates. These updated data inputs increase the hour burden by 522 hours compared with the prior submission and reduce the cost burden by $802 compared with the prior submission.

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

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

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

The OMB expiration date will be published in the Federal Register following OMB approval.

730,346 notices = $18,259

18. Explain each exception to the certification statement identified in Item 19.

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS.

Not applicable.