Supporting Statement for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs (CMS-10558/OMB control number 0938-1284)

A. Background

On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA; P.L. 111-148) was signed into law and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) was signed into law. The two laws implement various health insurance policies.

45 C.F.R. § 156.122(d)(1)-(2) and 156.230(c) as finalized in the rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 (CMS-9934-F), established standards for qualified health plan (QHP) issuers for the submission of provider and formulary data in a machine-readable format to the Department of Health and Human Services (HHS) and for posting the data on issuer websites. These standards provide greater transparency for consumers, including by allowing software developers to access formulary and provider data to create innovative and informative tools. On September 30, 2015, the Office of Management and Budget (OMB) granted approval to the data collection Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFE QHPs under OMB control number 0938-1284. OMB approval was granted again on November 3, 2017. The Centers for Medicare and Medicaid Services (CMS) is continuing that information collection request (ICR) in connection with these machine-readable standards.

B. Justification

1. <u>Need and legal basis</u>

Issuers are required to produce certain data to CMS in a machine-readable format to increase and enhance transparency of OHP drug formulary information and of information about providers under health plans. Under 45 C.F.R. § 156.122(d), QHP issuers, including Small Business Health Options Program (SHOP) issuers but excluding stand-alone dental plans (SADP) issuers, are required to publish an up-to-date, accurate, and complete list of all covered drugs, known as formularies.¹ Section 156.122(d)(1) states that formularies must list all drugs that fall under the category of essential health benefits (EHB), and list all drug names currently covered by the plan. Issuers must provide complete, accurate, and up-to-date formulary information for consumers on their website and must update this information not less than monthly. Further, §156.122(d)(2) requires that QHP issuer in the Federallyfacilitated Exchanges (FFE) publish their formulary drug list on its website in an HHS-specified format and submit this information to HHS in a format and at times determined by HHS. The machinereadable file or a format specified by HHS increases transparency by allowing software developers to access this information to create innovative and informative tools to help enrollees better understand plans' drug lists. QHP issuers must update the drug information in a machine-readable format not less than monthly. QHP issuers must submit drug information by "RxNorm Concept Unique Identifier" (RxCUI), including all drug formulations covered.

¹ Note that 45 C.F.R. 156.122(d)(2) includes individual and SHOP QHPs, but does not include stand-alone dental plans (SADP). Therefore, SADP issuers are not required to provide drug formulary data in a machine-readable format.

In addition, 45 C.F.R. § 156.230(b)(1) requires QHP issuers, including Small Business Health Options Program (SHOP) issuers and stand-alone dental plans (SADP) issuers, to publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, States, the Exchange, CMS, and the Office of Personnel Management (OPM). Section 156.230(b)(2) specifies that an issuer must update the directory information at least once a month. Section 156.230(c) requires issuers to make information about providers in its provider networks available to HHS in a specified format at times determined by HHS, and to make the information available on their websites. The machine-readable file increases transparency by allowing software developers to access formulary and provider data, to create innovative and informative tools to assist enrollees in understanding plans' provider networks.

2. <u>Information Uses</u>

Software developers and CMS access this information to create and maintain tools to help enrollees better understand the availability of drugs and providers in a specific plan.

3. <u>Use of Information Technology</u>

The availability of provider and formulary information aids consumers in efficiently selecting and using their QHP benefits.

Establishing machine-readable files with this data provides the opportunity for third parties to create resources that aggregate information on different plans and thus improve transparency.

4. <u>Duplication of Efforts</u>

We anticipate no duplication of effort for issuers. Issuers are not requested to provide provider directory and drug formulary information in a machine-readable format under any other CMS program.

5. <u>Small Business</u>

This information collection will not have a significant impact on small businesses.

6. <u>Less Frequent Collection</u>

The burden associated with this information collection consists of QHP issuers updating provider and formulary information, which QHP issuers are required to make available to consumers and to CMS not less than monthly. Because provider contracts and formularies change frequently, a less frequent information collection increases inaccuracy of data over time.

7. <u>Special Circumstances</u>

There are no special circumstances.

8. <u>Federal Register/Outside Consultation</u>

A 60-day notice was published in the Federal Register on July 17, 2020 (85 FR 43581). No comments were received. A 30-day Notice will be published in the Federal Register on November 27, 2020 (85 FR 76079) for the public to submit written comment on the information collection requirements.

No additional outside consultation was sought.

9. Payments/Gifts to Respondents

No payments and/or gifts will be provided to respondents.

10. <u>Confidentiality</u>

To the extent of the applicable law and HHS policies, we will maintain consumer privacy with respect to the information disclosed.

11. <u>Sensitive Questions</u>

There are no sensitive questions included in this information collection effort.

12. <u>Burden Estimates (Hours & Wages)</u>

Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the May 2019 National Industry-Specific Occupational Employment and Wage Estimates (Bureau of Labor Statistics (BLS)² (https://www.bls.gov/oes/current/oes_nat.htm#11-0000).

Table 1: Adjusted Hourly Wages Used in Burden Estimates

OES Designation	Occupational Code	Mean Hourly Wage (\$/hour)	Fringe Benefits and Overhead (\$/hour)	Adjusted Hourly Wage (\$/hour)
Pharmacist	29-1051	\$60.34	\$60.34	\$120.68
Operations Research Analyst/ Health Policy Analyst	15-2031	\$43.56	\$43.56	\$87.12
Computer Programmer	15-1251	\$44.53	\$44.53	\$89.06
General and Operations (Senior) Manager	11-1021	\$59.15	\$59.15	\$118.30

The following section of this document contains an estimate of the burden imposed by the associated ICRs. The burden estimates reflect the time and effort for QHP issuers to update and publish the appropriate data, and submit it to CMS.

² New Bureau of Labor Statistics employment data was released following the publication of the 60-day Federal Register Notice and required revising the wage rates and burden estimates.

We estimate 175 QHP issuers will be subject to the requirement to update and publish both provider directory data and formulary data monthly, and submit it to CMS, based on the number of issuers that were approved to offer QHPs in the 2020 plan year. We estimate that 201 SADP issuers will be subject to the requirement to update and publish only provider directory data monthly and submit it to CMS, based on the number of issuers that were approved to offer SADPs in the 2020 plan year. Information regarding the data fields that we propose issuers provide is contained in Appendix A. Appendix A is also posted on: https://github.com/CMSgov/QHP-provider-formulary-APIs/tree/2017-changes. Issuers will report their URLs annually and communicate their URLs for their JSON file locations through an online submission form located at https://marketplace.cms.gov/submission/. The form contents can also be found in Appendix B.

We estimate that about 15 new QHP issuers will need to fulfill the formulary and provider directory data requirements for the first time each year of this ICR, based on the rate of new issuers entering the marketplace in prior years. We estimate that it will take a pharmacist 8 hours (at \$120.68 per hour), a health policy analyst 28 hours (at \$87.12 per hour), an operations research analyst 2 hours (at \$87.12 per hour), a computer programmer 94 hours (at \$89.06 per hour), and a senior manager 4 hours (at \$118.30 per hour) for new QHPs to fulfill these requirements in the first year. The total estimated burden is \$12,423.88 per issuer per year, or \$186,358.20 for all new QHP issuers.

Pursuant to 45 C.F.R. 156.230(c), QHP issuers, including new QHP issuers, must publish and update provider directory data in the machine readable format directed by CMS, on a monthly basis. In addition, 45 C.F.R. 156.122(d)(1)-(2) requires QHP issuers, including new QHP issuers, to publish and update formulary data in a machine readable format designated by CMS, on a monthly basis. The table below displays the burden for the new QHP issuers in their first year on the Exchange relating to these regulatory requirements.

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (per Respondent)	Total Burden Cost (All Respondents)
Pharmacist	1	\$120.68	8	\$965.44	\$14,481.60
Health Policy	1	\$87.12	28	\$2,439.36	\$36,590.40
Analyst					
Operations	1	\$87.12	2	\$174.24	\$2,613.60
Research Analyst					
Computer	1	\$89.06	94	\$8,371.64	\$125,574.60
Programmer					
Senior Manager	1	\$118.30	4	\$473.20	\$7,098.00
Total			136		
Total Burden			2,040	\$12,423.88	\$186,358.20

Table 2a: Burden to New QHP Issuers in their First Year

We estimate that about five new SADP issuers will need to fulfill the provider directory data requirements for the first time each year of this ICR, based on the rate of new issuers entering the marketplace in prior years. We estimate that it will take a health policy analyst 14 hours (at \$87.12 per

hour), an operations research analyst one hour (at \$87.12 per hour), a computer programmer 47 hours (at \$89.06 per hour), and a senior manager 2 hours (at \$118.30 per hour) for new SADPs to fulfill these requirements in the first year. The total estimated burden is \$5,729.22 per issuer per year, or \$28,646.10 for all new SADP issuers.

Pursuant to 45 C.F.R. 156.230(c), SADP issuers, including new SADP issuers, must publish and update provider directory data in the machine readable format directed by CMS, on a monthly basis. The table below displays the burden for the new SADP issuers in their first year on the Exchange relating to this regulatory requirement.

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (per Respondent)	Total Burden Cost (All Respondents)
Health Policy	1	\$87.12	14	\$1,219.68	\$6,098.40
Analyst					
Operations	1	\$87.12	1	\$87.12	\$435.60
Research Analyst					
Computer	1	\$89.06	47	\$4,185.82	\$20,929.10
Programmer					
Senior Manager	1	\$118.30	2	\$236.60	\$1,183.00
Total			64		
Total Burden			320	\$5,729.22	\$28,646.10

Table 2b: Burden to New SADP Issuers in their First Year

We estimate that 160 existing QHP issuers will have the infrastructure in place to fulfill the provider directory and formulary data requirements. For each issuer, we estimate that it will take a health policy analyst 18 hours per year (at \$87.12 per hour) and a computer programmer 18 hours per year (at \$89.06 per hour) to fulfill these requirements. This is a total of \$3,171.24 per issuer per year, or \$507,398.40 for 160 QHP issuers.

Pursuant to 45 C.F.R. 156.230(c), QHP issuers must publish and update provider directory data in the machine readable format directed by CMS, on a monthly basis. In addition, 45 C.F.R. 156.122(d)(1)-(2) requires QHP issuers to publish and update formulary data in a machine readable format as designated by CMS, on a monthly basis. The table below displays the burden for existing QHP issuers relating to these regulatory requirements.

Table 3a: Burden to Existing QHP Issuers in Year 1

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (per Respondent)	Total Burden Cost (All Respondents)
Health Policy	1	\$87.12	18	\$1,568.16	\$250,905.60
Analyst					
Computer	1	\$89.06	18	\$1,603.08	\$256,492.80

Programmer				
Total		36		
Total Burden		5,760	\$3,171.24	\$507,398.40

Similarly, we estimate that 196 existing SADP issuers will have the infrastructure in place to fulfill the provider directory data requirements. For each issuer, we estimate that it will take a health policy analyst 9 hours per year (at \$87.12 per hour) and a computer programmer 9 hours per year (at \$89.06 per hour) to fulfill these requirements. This is a total of \$1,585.62 per issuer per year, or \$310,781.52 for 196 SADP issuers.

Pursuant to 45 C.F.R. 156.230(c), SADP issuers must publish and update provider directory data in the machine readable format directed by CMS, on a monthly basis. The table below displays the burden for existing SADP issuers relating to this regulatory requirement.

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (per Respondent)	Total Burden Cost (All Respondents)
Health Policy	1	\$87.12	9	\$784.08	\$153,679.68
Analyst					
Computer	1	\$89.06	9	\$801.54	\$157,101.84
Programmer					
Total			18		
Total Burden			3,528	\$1,585.62	\$310,781.52

Table 3b: Burden to Existing SADP Issuers in Year 1

In years two and three, we estimate that it will take a health policy analyst 18 hours per year (at \$87.12 per hour) and a computer programmer 18 hours per year (at \$89.06 per hour) to fulfill the provider directory and formulary data requirements for each QHP issuer. This is a total of \$3,171.24 per issuer per year, or \$554,967.00 for all 175 QHP issuers.

Pursuant to 45 C.F.R. 156.230(c), QHP issuers, including QHP issuers in years two and three on the Exchange, must publish and update provider directory data in the machine readable format directed by CMS, on a monthly basis. In addition, 45 C.F.R. 156.122(d)(1)-(2) requires QHP issuers to publish and update formulary data in a machine readable format designated by CMS, on a monthly basis. The table below displays the burden for QHP issuers in years two and three on the Exchange relating to these regulatory requirements.

Table 4a: Burden to QHP Issuers in Years 2 and 3

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (per Respondent)	Total Burden Cost (All Respondents)
Health Policy	1	\$87.12	18	\$1,568.16	\$274,428.00

Analyst					
Computer	1	\$89.06	18	\$1,603.08	\$280,539.00
Programmer					
Total			36		
Total Hours			12,600	\$3,171.24	\$554,967.00

We estimate that in years two and three, it will take a health policy analyst 9 hours per year (at \$87.12 per hour) and a computer programmer 9 hours per year (at \$89.06 per hour) to fulfill the provider directory data requirements for each SADP issuer. This is a total of \$1,585.62 per issuer per year, or \$318,709.62 for all 201 SADP issuers.

Pursuant to 45 C.F.R. 156.230(c), SADP issuers, including SADP issuers in years two and three on the Exchange, must publish and update provider directory data in the machine readable format directed by CMS, on a monthly basis. The following table displays the burden for the SADP issuers in years two and three on the Exchange relating to this regulatory requirement.

Table 4b: Burden to SADP Issuers in Years 2 and 3

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (per Respondent)	Total Burden Cost (All Respondents)
Health Policy	201	\$87.12	9	\$784.08	\$157,600.08
Analyst					
Computer	201	\$89.06	9	\$801.54	\$161,109.54
Programmer					
Total			18		
Total Burden			7,236	\$1,585.62	\$318,709.62

The aggregate cost for years one through three across all 376 issuers is 2,780,537.46 (1,033,184.22 in year one + $873,676.62 \times 2$ for years two and three).

The table below provides a summary of the estimates within this package.

Table 5: Summary of Total Burden

Table Number: Name	CFR Section	Burden Hours	Burden Cost
Table 2a: New QHP Issuers in First Year	45 C.F.R. § 156.122(d)(1)- (2) and 156.230(c)	2,040	\$186,358.20
Table 2b: New SADP Issuers in First Year	45 C.F.R. § 156.230(c)	320	\$28,646.10
Table 3a: Existing QHP Issuers in Year 1	45 C.F.R. § 156.122(d)(1)- (2) and 156.230(c)	5,760	\$507,398.40
Table 3b: Existing SADP Issuers in Year 1	45 C.F.R. § 156.230(c)	3,528	\$310,781.52

Table 4a: QHP Issuers in Years 2 and 3	45 C.F.R. § 156.122(d)(1)- (2) and 156.230(c)	12,600	\$1,109,934.00
Table 4b: SADP Issuers in Years 2 and 3	45 C.F.R. § 156.230(c)	7,236	\$637,419.24
Total (3-year total)		31,484	\$2,780,537.46

13. <u>Capital Costs</u>

There are no additional capital costs associated with these information collections.

14. <u>Cost to Federal Government</u>

There are no additional costs to the federal government.

15. <u>Changes to Burden</u>

The total three-year burden hours have been reduced from 82,576 hours to 31,484 hours, a reduction in burden of 51,092 hours. This change is due in part to fewer issuers (397 in the previously approved package compared to 376 in this current request) participating in the health insurance Exchanges. In addition, the burden has been calculated separately for the 175 QHP issuers and 201 SADP issuers on the Exchanges. Because SADP issuers are not required to make updated formulary information available to consumers and to CMS, we estimate that SADP issuers will require no pharmacist burden hours and will require half the burden hours estimated for QHPs for the remaining labor categories (per respondent).

16. <u>Publication/Tabulation Dates</u>

The updating of provider and formulary data by QHPs occurs monthly. The updating of provider data by SADPs also occurs monthly. The data collected will be submitted to CMS and made public through the QHP and SADP issuers' websites on a recurring basis to ensure the most up-to-date information is available to Marketplace consumers.

17. <u>Expiration Date</u>

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