

Supporting Statement – Part A
Information Collection Requirement for Mid-Year Formulary Change
Reporting and Notice Requirement
CMS-10696/OMB Control Number: 0938-NEW

A. Background

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (P.L. 111-148). On March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (P.L.111-152) was signed into law. The two laws are collectively referred to as the Affordable Care Act. The Affordable Care Act (ACA) established new competitive private health insurance Exchanges, which gave millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)— private health and dental insurance plans that have been certified as meeting certain standards.

In the proposed rule, the *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020* (CMS-9926-P), we propose to add §147.106(e)(5) to allow a health insurance issuers, beginning with plan years on or after January 1, 2020, the flexibility to update their prescription drug formularies by allowing certain mid-year formulary changes in an effort to optimize the use of new generic drugs as they become available, and incentivize enrollees to use lower cost drugs on the formulary by modifying the application of the annual limitation on cost-sharing. We propose allowing issuers to make the following changes during the plan year: add a generic equivalent drug to the formulary, remove the brand name drug from the formulary when only when a generic equivalent becomes available and is added to the formulary, or add a generic equivalent to a formulary and move the corresponding brand name drug to a different cost-sharing tier.

At §147.106(e)(5), we propose for plan years beginning on or after January 1, 2020, a health insurance issuer may make mid-year formulary changes by notifying the plan enrollees of changes a minimum 60 days prior to initiating a change that removes the brand name drug from the formulary when a generic equivalent becomes available; or adds a generic equivalent drug to the formulary and moves the brand drug to a higher formulary drug tier. Providing a pre-notification before changes to the formulary are implemented will allow enrollees to begin working with their prescribing healthcare provider on any exception request processes before the change occurs.

The Centers for Medicare and Medicaid Services (CMS) is creating a new information collection request (ICR) in connection with these standards. The burden estimate for this new ICR included in this package reflects the additional time and effort for QHP issuers to provide notifications to enrollees.

B. Justification

1. Need and Legal Basis

Under proposed §147.106(e)(5), for plan years beginning on or after January 1, 2020, a health insurance issuer must notify their enrollees no less than 60 calendar days prior to removing a brand drug from the formulary or placing the brand drug on a higher cost sharing tier. We believe that enrollees should be made aware of any drug formulary changes that may have impacted their plan selection and enrollment, or any other associated restrictions on access to brand drugs. Therefore, we are proposing a requirement for issuers to notify their enrollees of such changes. Enrollees would retain the option to request coverage for a brand name drug that was removed from the formulary through the state's coverage appeal process under §147.136 or the drug exception request process under §156.122(c).

2. Information Users

The notifications that a health insurance issuer will be required to send under this information collection will be sent to enrollees who may be adversely affected by brand drugs being moved to a higher cost-sharing tier or removal of a drug from the formulary. The notifications are intended to inform the consumer about such changes to his or her health insurance coverage. Enrollees would retain the option to request coverage for a brand name drug that was removed from the formulary through the state's coverage appeal process under §147.136 or the drug exception request process under §156.122(c).

3. Use of Information Technology

CMS anticipates that health insurance issuers will use their claims data systems to identify enrollees that need to be notified. The notification must be sent to the enrollee electronically or by mail, both 60 days prior to brand drug formulary changes.

4. Duplication of Efforts

Notices to enrollees under proposed §147.106(e)(5), do not duplicate any other Federal effort.

5. Small Businesses

We do not anticipate that small businesses will be significantly burdened by this data collection.

6. Less Frequent Collection

The burden associated with this information collection consists of health insurance issuers notifying enrollees about the plan's change of access of a brand drug by moving the drug to a higher cost-sharing tier or removal of a drug from the formulary. We recognize that the notification of the change is a good faith effort, as there are certain situations that the issuer cannot anticipate at the beginning of a plan year. For these reasons, the proposed regulation requires the notification

calendar days prior to changing access to a brand drug, and providing an exceptions process, pursuant to the applicable coverage appeal process under §147.136 or the drug exception request process under §156.122(c).

7. Special Circumstances

There are no anticipated special circumstances

8. Federal Register/Outside Consultation

The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 (CMS-9926-P) proposed rule published January 24, 2019. CMS proposed §147.106(e) (5), and is awaiting comments on the proposed information collection. CMS will consider any comments received during the 60-day comment period.

9. Payments/Gifts to Respondents

No payments and/or gifts will be provided.

10. Confidentiality

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

11. Sensitive Questions

No sensitive questions are included in these notice requirements.

12. Burden Estimates (Hours & Wages)

We generally used data from the Bureau of Labor Statistics to derive average labor costs (including fringe benefits) for estimating the burden associated with the ICRs.

In an effort to optimize the use of new generic drugs as they become available, we proposed to allow issuers, beginning with plan years on or after January 1, 2020, to update their prescription drug formularies by allowing certain mid-year formulary changes, subject to applicable state law.

We propose that a health insurance issuer that makes one of the following mid-year drug formulary changes would be required to send a written notice to enrollees 60 days prior to implementing any of the following drug formulary changes:

- Adding a generic equivalent drug to the formulary, while removing the brand name drug from the formulary; or
- Adding a generic equivalent to a formulary and moving the equivalent brand name drug to a different cost-sharing tier.

Such changes would not be permitted to exceed the scope of what would otherwise be a uniform modification, and enrollees would retain the option to request coverage for a brand name drug that was removed from the formulary through the applicable coverage appeal process under §147.136 or the drug exception request process under §156.122(c).

Based on the 2016 Medical Loss Ratio (MLR) totals, there are 520 health insurance issuers with estimated 75.6 million enrollees. Given the approval trends from 2016 through 2018, we also estimate that the Food and Drug Administration approves an average of 76 first time generic drug applications per calendar year, allowing a first time generic equivalent of a brand drug to be manufactured.¹ However, not all of these drugs are suitable for a drug formulary; some are only administered in a clinical setting, and others may be approved for over-the counter (OTC) use. We also considered that not all issuers will opt to make mid-year formulary changes. In reviewing the recent first time FDA generic equivalent approvals for 2018, 60 percent, or 37 generic equivalent drugs are available by prescription and could potentially be found on an issuers' formulary, resulting in a mid-year formulary change. If finalized as proposed, all enrollees would receive a notice regarding the mid-year formulary change.

Issuers would have two options to make formulary changes, therefore we have provided two notice cost estimates for removing a brand drug from the formulary and for changing the cost-sharing tier for a brand drug.

Notice of Change: Removal of a brand drug from the formulary

A health insurance issuer would be required to provide a written notice 60 days in advance. This notice would be required to identify the name of the brand drug that is the subject of the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in §147.136 or

¹ See ANDA (Generic) Drug Approval Reports-2018. Available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/default.htm>. See also ANDA (Generic Drug Approval Reports Previous Years-2016-17. Available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm050527.htm>.

the exceptions processes outlined in §156.122(c), enrollees and dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan. Issuers also would be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process under §147.136 or the drug exception request process under §156.122(c). Therefore, we estimate that a “Notice of Change: Removal of a brand drug from the formulary,” would require issuers 10 hours of clerical labor (at a cost of \$39.12 per hour) to prepare the custom notice using an existing standard notice or a standard notice provided by the issuer’s state. It would take an estimated 2 hour for a senior manager (at a cost of \$118.70 per hour) to review the notice template. We also estimate that it would take a computer programmer 10 hours (at a cost \$84.16 per hour) to write and test a program to automate the electronic notices. The total annual burden for each issuer to prepare the template would be 22 hours with an equivalent cost of approximately \$1,470. For all 520 health insurance issuers, the total annual burden would be 11,440 hours with an equivalent cost of approximately \$764,504.

Notice of Change: Change to cost-sharing tier for a brand drug

A health insurance issuer would provide the notice 60-days prior to adding a generic equivalent to a formulary, and moving the equivalent brand name drug to a different cost-sharing tier. Therefore, we estimate that a “Notice of Change: Change to cost-sharing tier for a brand drug,” would require 6 hours of clerical labor (at a cost of \$39.12 per hour) to prepare the custom notice using an existing standard notice or a standard notice provided by the issuer’s state. It would take an estimated 2 hours for a senior manager (at a cost of \$118.70 per hour) to review the notice template. We also estimate that it would take a computer programmer 10 hours (at a cost \$84.16 per hour) to write and test a program to automate the electronic notices. The total annual burden for each issuer to prepare the template would be 18 hours with an equivalent cost of approximately \$1,314. For all 520 health insurance issuers, the total annual burden would be 9,360 hours with an equivalent cost of approximately \$683,134.

As a subset of this notice requirement, at §156.122(d)(3) we propose that QHP issuers in the FFEs would be required to notify HHS annually in an HHS-specified format of any mid-year formulary changes made in the prior plan year consistent with the policy proposed at §147.106(e) that would allow an issuer to make mid-year drug formulary changes. QHP issuers in the FFEs would be required to report the name of the drug being removed from the formulary, dosage, name of the generic equivalent, the Rx Norm Concept Unique Identifier (RxCUI) associated with the brand and generic drug, if the brand drug was moved to a higher cost sharing tier or removed from the formulary. Issuers would be required to submit the formulary changes in a template as specified by HHS. We estimate 66 QHP issuers (not including SADPs, but encompassing both individual and SHOP markets) will offer QHPs in an FFE and thus be subject to this requirement. The estimate of 66 is based on the number of issuers whose QHP issuers in an FFE, that appeared on HealthCare.gov in the 2019 plan year.

We estimate that it will take 42 hours per year for a QHP issuer in an FFE to meet this reporting requirement, which will occur annually. On average, we estimate that it will take an Information and Records Clerk 36 hours (at \$39.12 an hour), and a Senior Manager 6 hours (at \$118.70 an hour) to fulfill these requirements. The total estimated annual burden is 42 hours with an equivalent cost of approximately \$2,121 per reporting entity. The aggregate annual burden for all issuers would be 2,772 hours with an equivalent cost of approximately \$139,954.

TABLE 1: Estimated Annualized Burden for Notices of Change for All Health Plans

Respondent	Type of notice	Number of respondents	Number of notices per respondent	Burden per notice (Hours)	Cost per notice	Total burden for all respondents	Total Labor Cost for all respondents
Health Insurance Issuer	Notice of Change: Removal of a brand drug from the formulary	520	1	22	\$1470.20	11,440	\$764,504.00
Health Insurance Issuer	Notice of Change: Change to Cost-sharing tier for a brand drug	520	1	18	\$1313.72	9,360	\$683,134.40
Total		520				20,800	\$1,447,638.40

TABLE 2: Estimated Annualized Burden for Mid-year Formulary Change Reporting to QHP FFE Issuers

Labor Category	Number of Employees	Hourly Labor Costs (hourly rate + 100% fringe benefits)	Burden Hours	Total Burden Costs	Total Burden Cost (per year)
Information and Records Clerk	1	\$39.12	36	\$1408.32	
Senior Manager	1	\$118.70	6	\$712.20	
Total per Issuer			42	\$2120.52	
Total for the 66 QHP FFE Issuers					\$ 139,954.32

13. Capital Costs

Notice of Change: Removal of a brand drug from the formulary

The cost to print and send the notice would include \$0.05 per page and \$0.55 to mail. We assume that approximately half of the notices sent would be of this type, with a mailing cost of approximately \$7,740,700. The total annual cost for all issuers would be approximately \$8,505,204.

Notice of Change: Change to cost-sharing tier for a brand drug

The cost to print and send the notice would include \$0.05 per 1-page and \$0.55 per notice to mail. We assume that approximately half of the notices sent would be of this type, with a mailing cost of approximately \$7,740,700. The total annual cost for all issuers would be approximately \$8,423,834.

14. Cost to Federal Government

There are no additional costs to the Federal Government.

15. Changes to Burden

This is a new data collection

16. Publication/Tabulation Dates

The results of the data collection will not be published.

17. Expiration Date

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