Supporting Statement for Non-Standardized Plan Option Limit Exceptions (CMS-10878/OMB control number: 0938-1461)

A. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, "Affordable Care Act"), expanded access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), also called Marketplaces, including the Small Business Health Options Program (SHOP). The Exchanges, which became operational on January 1, 2014, enhance competition in the health insurance market, expand access to affordable health insurance for millions of Americans, and provide consumers with a place to easily compare and shop for health insurance coverage.

Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as qualified health plans (QHPs). Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA for, among other things, the offering of QHPs through such Exchanges.

In the *HHS Notice of Benefit and Payment Parameters for 2024 Final Rule* (2024 Payment Notice Final Rule), HHS exercised its authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to limit the number of non-standardized plan options that issuers of QHPs can offer through Exchanges on the Federal platform, including both through Federally-facilitated Exchanges (FFEs) and State-Based Exchanges on the Federal platform (SBE-FPs), to four non-standardized plan options per product network type (as described in the definition of "product" at 45 C.F.R. 144.103), metal level (excluding catastrophic plans), inclusion of dental and/or vision benefit coverage, and service area for plan year (PY) 2024, and two for PY 2025 and subsequent plan years.

This information collection request (ICR) serves as the formal request for a new information collection clearance associated with the *HHS Notice of Benefit and Payment Parameters for 2025 Final Rule* (2025 Payment Notice Final Rule) regarding the authority to allow HHS to collect the necessary information to enable QHP issuers to request to be excepted from the non-standardized plan option limit of two per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent years, if they so choose.

B. Justification

1. Need and Legal Basis

Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA for, among other things, the offering of QHPs through such Exchanges.

In the 2024 Payment Notice Final Rule, HHS exercised its authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to limit the number of non-standardized plan options that issuers of QHPs can offer through Exchanges on the Federal platform, including both through FFEs and SBE-FPs, to four non-standardized plan options per product network type (as described in the definition of "product" at 45 C.F.R. 144.103), metal level (excluding catastrophic plans), inclusion of dental and/or vision benefit coverage, and service area for PY 2024, and two for PY 2025 and subsequent plan years.

As part of the 2025 Payment Notice Final Rule, we propose a new ICR and request a 30-day public comment period on the requirements at 45 C.F.R. 156.202(d) through (e) to permit FFE and SBE-FP issuers to offer more than two non-standardized plan options per product network type, metal level, inclusion of dental and vision benefit coverage, and service area for PY 2025 and subsequent plan years, if issuers demonstrate that these additional non-standardized plans beyond the limit at 45 C.F.R. 156.202(b) have specific design features that would substantially benefit consumers with chronic and high-cost conditions. An issuer that seeks to utilize this exceptions process is required to submit a written justification in a form and manner and at a time prescribed by HHS at § 156.202(e).

This ICR will utilize the collection instrument in Appendix A. Non-Standardized Plan Option Limit Exception Justification Form and Actuarial Memorandum. FFE and SBE-FP issuers will be required to submit these materials electronically in the Marketplace Plan Management System (MPMS) as part of QHP certification.

2. Information Users

This ICR will provide HHS the authority necessary to collect information from QHP issuers requesting to be excepted from the non-standardized plan option limit of two per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent years, if they so choose. Collecting the required information in the justification form and actuarial memorandum will enable HHS to ensure QHP issuers are meeting the requirements at § 156.202(d) through (e) to be granted an exception to the non-standardized plan option limit at 45 C.F.R. 156.202(b).

3. Use of Information Technology

HHS anticipates that a majority of the systems, notices, and information collection required will be automated. All of the information that is required by this collection of information will be submitted electronically. HHS staff will analyze or review the data, including the aforementioned justification form and actuarial memorandum, in the same manner by which it was submitted and communicate with States, health insurance issuers, and other entities using e-mail, telephone, or other electronic means.

4. Duplication of Efforts

This information collection does not duplicate any other Federal effort.

5. Small Businesses

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

6. Less Frequent Collection

If information is collected on a less frequent basis, HHS will be unable to allow QHP issuers' request to be excepted from the non-standardized plan option limit of two per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent years, which could result in the issuers being unable to offer non-standardized plan options that would benefit consumers with chronic and high-cost conditions. Therefore, this information must be collected on an annual basis to allow issuers to submit a request to be excepted from the non-standardized plan option limit and offer these additional plans, if they so choose.

7. Special Circumstances

There are no anticipated special circumstances.

8. Federal Register/Outside Consultation

This ICR was published as part of the Payment Notice Proposed Rule in the Federal Register on 11/24/2023 (88 FR 82510) for the public to submit written comment as part of a first-round public comment period. No public comments were received.

This ICR will be published as part of the Payment Notice Final Rule in the Federal Register on 4/15/2024 (89 FR 26218) as part of a second-round public comment period for the public to submit written comment.

No additional outside consultation was sought.

9. Payments/Gifts to Respondents

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

10. Confidentiality

All information collected will be kept private in accordance with regulations at 45 C.F.R. 155.260, Privacy and Security of Personally Identifiable Information. Pursuant to this regulation, Marketplaces may only use or disclose personally identifiable information to the extent that such information is necessary to carry out their statutorily and regulatorily mandated functions.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

We used the Bureau of Labor Statistics (BLS), Occupational Employment Statistics, May 2022 (https://www.bls.gov/oes/current/oes_stru.htm) to estimate the burden for this information collection. The median hourly wage (which also includes a 100% fringe benefit rate) is $109.60 per hour for an actuary (OES occupational code 15-2011); $94.32 for a general and operations manager (OES occupational code 11-1021); and $206.22 for a general internal medicine physician (OES occupational code 29-1216). See Table 1.

Table 1. Adjusted Hourly Wages Used in Burden Estimates.

Occupational Title	Occupational Code	Median Hourly Wage ($/hour)	Fringe Benefits & Overhead (100%) ($/hour)	Adjusted Hourly Wage ($/hour)
Actuary	15-2011	$54.80	$54.80	$109.60
General and Operations Manager	11-1021	$47.16	$47.16	$94.32
General Internal Medicine Physicians	29-1216	$103.11	$103.11	$206.22

Non-Standardized Plan Option Limit Exceptions (§ 156.202): As part of the 2025 Payment Notice Final Rule, we propose a new ICR and request a 30-day public comment period on the requirements at 45 C.F.R. 156.202(d) through (e) to permit FFE and SBE-FP issuers to offer more than two non-standardized plan options per product network type, metal level, inclusion of dental and vision benefit coverage, and service area for PY 2025 and subsequent plan years, if issuers demonstrate that these additional non-standardized plans beyond the limit at 45 C.F.R. 156.202(b) have specific design features that would substantially benefit consumers with chronic and high-cost conditions.

Specifically, at § 156.202(d), for PY 2025 and subsequent years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, and service area.

We finalized several specifications for issuers seeking to utilize this exceptions process at § 156.202(d)(1) through (6). Specifically, at subparagraph (1), the 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions will be evaluated at the level of total out-of-pocket costs for the treatment of the chronic and high-cost condition for a population of enrollees with the relevant chronic and high-cost condition. At subparagraph (2), the reduction must not be limited to a part of the year, or an otherwise limited scope of benefits. At subparagraph (3), the reduction in cost sharing for these benefits cannot be conditioned on a consumer having a particular diagnosis.

At subparagraph (4), the required reduction in cost sharing only applies to the standard variant of the

plan for which an issuer seeks an exception, and not to the income-based cost-sharing reduction plan variations required by § 156.420(a), nor to the zero and limited cost sharing plan variations required by § 156.420(b). At subparagraph (5), issuers are limited to one exception per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, for each chronic and high-cost condition. At subparagraph (6), the chronic and high-cost conditions that may qualify an issuer for this exception will be determined by HHS. Refer to § 156.202 of the preamble to 2025 Payment Notice Final Rule for a more detailed discussion regarding these requirements.

Additionally, at § 156.202(e), an issuer that seeks to utilize this exceptions process is required to submit a written justification in a form and manner and at a time prescribed by HHS. At subparagraph (1), the written justification must identify the specific chronic and high-cost condition that their additional non-standardized plan option offers substantially reduced cost sharing for.

At subparagraph (2), the written justification must identify which benefits in the Plans and Benefits Template are discounted to provide reduced treatment-specific cost sharing for individuals with the specified chronic and high-cost condition. These discounts must be relative to the treatment-specific cost sharing for the same corresponding benefits in the issuer's other non-standardized plan offerings in the same product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area. For the purposes of this standard, treatment specific cost sharing consists of the costs for obtaining services that pertain to the treatment of a particular chronic and high-cost disease – but not the costs for obtaining services that do not pertain to the treatment of the relevant condition. The issuer must identify all services for which the benefits substantially reduce cost sharing in the Plans and Benefits Template. These benefits must reasonably encompass a complete list of relevant services pertaining to the treatment of the relevant condition.

At subparagraph (3), the written justification must explain how the reduced cost sharing for these services pertains to clinically indicated guidelines and a representative treatment scenario for treatment of the specified chronic and high-cost condition (include any relevant studies, guidelines, or supplementary documents to support the application, as applicable). For the purposes of this standard, a representative treatment scenario is an annual course of treatment for a chronic and high-cost condition.

At subparagraph (4), the written justification must include a corresponding actuarial memorandum that explains the underlying actuarial assumptions made in the design of the plan the issuer is requesting to except. In this memorandum, an issuer must demonstrate how the benefits that are discounted to provide reduced treatment-specific cost sharing of at least 25 percent identified at § 156.202(e)(2) for the treatment of the condition identified at § 156.202(e)(1) under the excepted plan compared to the identified in-limit offering in the same product network type, metal level, inclusion of dental and/or vision coverage, and service area. This demonstration must specifically be in reference to the specific population that would be seeking treatment for the relevant condition and not the general population. This memorandum also includes an actuarial opinion confirming that this analysis was prepared in accordance with the appropriate Actuarial Standards of Practice and the profession's Code of Professional Conduct.

We estimate that approximately 50 FFE and SBE-FP issuers would request to be excepted from the non-standardized plan option limit in order to offer these additional plans annually. In order for an issuer to complete the necessary documentation to submit a request to be excepted from

the non-standardized plan option limit at § 156.202(b) in accordance with the proposed requirements at § 156.202(d) through (e), we estimate that it would take an actuary five hours annually at a median hourly cost of $109.60 per hour (amounting to $548.00 annually); a general and operations manager ten hours annually at a median hourly cost of $94.32 per hour (amounting to $943.20 annually); and a general internal medicine physician two hours annually at a median hourly cost of $206.22 (amounting to $412.44 annually). We estimate a total cost of $1,903.64 per issuer annually to submit a request to be excepted from the non-standardized plan option limit. Altogether, we estimate that this information collection has an annual burden of 850 hours with a total cost of $95,182.00 for all respondents annually. Furthermore, we estimate a total burden of 2,550 hours with a total cost $285,546.00 for all respondents for the duration of this collection over three years. See Table 2.

Table 2. Annual Burden for an Issuer to Submit the Justification Form and Actuarial Memorandum as Part of the Request to be Excepted from the Non-Standardized Plan Option Limit.

Occupational Title	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe Benefits)	Burden Hours	Total Burden Cost (per Respondent)	Total Burden Costs (All Respondents)
Actuary	50	$109.60	5	$548.00	$27,400.00
General and Operations Manager	50	$94.32	10	$943.20	$47,160.00
General Internal Medicine Physician	50	$206.22	2	$412.44	$20,622.00
Total - Annual			**850**		**$95,182.00**
Total – Three Years			**2,550**		**$285,546.00**

13. Capital Costs

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

14. Cost to Federal Government

We estimate that the operations and maintenance costs for the data collection tool and the data collection support to have a total cost to the federal government of $15,405.00 annually. The calculations for CMS employees' hourly salary was obtained from the OPM website: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/html/DCB_h.aspx

Table 3. Administrative Burden Costs for the Federal Government Associated with the Collection.

Task	**Estimated Cost**
Operations, maintenance, and data collection support	
2 GS-13 (step 7): 2 x $135.66[1] x 50 hours	$13,566.00
Managerial review and oversight	
1 GS-15 (step 7): $183.90[1] x 10 hours	$1,839.00
Total Costs to Government	**$15,405.00**

[1] Hourly basic rate + 100% fringe benefit rate.

15. Changes to Burden

There are no changes to burden as this is a new information collection.

16. Publication/Tabulation Dates

There are no plans to publish the outcome of the data collection.

17. Expiration Date

The expiration date and OMB control number will appear on the first page of the instrument in the top, right corner.