**Supporting Statement – Part A**
**Medicaid Comprehensive Quality Strategy (CQS) and**
**Supporting Regulations in §§431.500, 431.502, 431.504, and 431.506**
**CMS-10553, OMB 0938-NEW**

This package is associated with a June 1, 2015 NPRM (CMS-2390-P; RIN 0938-AS25).

## Background

The Medicaid managed care proposed rule (CMS-2390-P) would modernize Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. In addition to changes to managed care regulations, this proposed rule would also require all states and territories to establish a comprehensive quality strategy (CQS) for the state's entire Medicaid program. States would review and revise the CQS at least once every three years, and would engage the public in drafting both original and revised CQS. This builds on the requirement in part 438 for a Medicaid managed care quality strategy, and would ensure that states and territories are engaged in goal setting and performance measurement for their entire Medicaid program, regardless of delivery system.

## A. Justification

1. Need and Legal Basis

   Section 1932(c)(1) requires states to develop and implement quality assessment and improvement strategies for their managed care arrangements.

   Section 1902(a)(4) requires such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the plan.

   Section 1902(a)(6) requires that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

   Section 1902(a)(19) requires such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients.

   Section 1902(a)(22) requires descriptions of the other standards and methods that the state will use to assure that medical or remedial care and services provided to recipients of medical assistance are of high quality.

2. Information Users

Medicaid beneficiaries and stakeholders use the information collected and reported to understand the state's quality improvement goals and objectives, and to understand how the state is measuring progress on its goals.

States use this information to help monitor and assess the performance of their Medicaid programs. This information may assist states in comparing the outcomes of different delivery systems and can assist them in identifying future performance improvement subjects.

CMS uses this information as a part of its oversight of Medicaid programs.

3. Use of Information Technology

States will post their final comprehensive quality strategies, and effectiveness evaluations of their strategies, on their Medicaid websites. This will ensure the public has electronic access to this information. States have discretion regarding their use of information technology for the public engagement process.

While there is discretion, we expect that states will generally submit their comprehensive quality strategies to CMS for review via email. No signature, electronic or written is required for this document.

4. Duplication of Efforts

States that contract with MCOs and/or PIHPs have been required to have and operate a Medicaid managed care quality strategy since 2002. The proposed comprehensive quality strategy regulations include a reference to the managed care quality strategy requirements to ensure that states create a single document for their entire Medicaid program, to ensure this work is not duplicated.

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

These information collection requirements do not affect small businesses.

6. Less Frequent Collection

The proposed rule would establish that the comprehensive quality strategy should be reviewed and revised at least once every three years. If this were to occur less frequently, progress on goals and the identification of new goals might not occur regularly, which would limit the utility of the strategy. The comprehensive quality strategy is a tool to help drive quality improvement, and as such should not be allowed to stagnate.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The NPRM is serving as the 60-day Federal Register notice which is scheduled to published June 1, 2015 (80 FR 31098). The NPRM was placed on public inspection on May 26 whereby comments are due July 27.

Comprehensive quality strategies for states with Medicaid managed care were discussed in State Health Official Letter 13-007: Quality Considerations for Medicaid and CHIP Programs. Some states already have experience with this type of quality strategy due to the inclusion of a CQS requirement in the special terms and conditions (STCs) for some section 1115 demonstrations. Additionally, CMS consulted informally with the National Association of Medicaid Directors (NAMD) regarding potential quality strategy requirements under consideration as part of the proposed rule.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information received by CMS is not confidential and its release would fall under the Freedom of Information Act. Additionally, states are required under these regulations to maintain the current CQS on their websites, where they must also post the findings of the CQS effectiveness evaluations conducted at least once every three years.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

*Wage Estimates*

To develop burden estimates, we used data from the U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

| Occupation Title | Occupation Code | Mean Hourly Wage ($/hr) | Fringe Benefit (at 100%) ($/hr) | Adjusted Hourly Wage ($/hr) |
|---|---|---|---|---|
| Business Operations Specialist | 13-1000 | 29.66 | 29.66 | 53.32 |
| Office and Administrative Support Worker | 43-9000 | 14.96 | 14.96 | 29.92 |

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

*Proposed Requirements and Burden Estimates*

Section 431.502 State comprehensive quality strategy

This section describes the general requirement for a state comprehensive quality strategy, including its basic elements.

Under section 431.502 all 56 states and territories (referred to throughout this section as "states") would have and operate a comprehensive quality strategy for all Medicaid beneficiaries in the state regardless of delivery system. This would replace the quality strategy focused exclusively on Medicaid managed care which currently exists at § 438.202.

Per section 431.502(a) each state would write and implement a comprehensive quality strategy. We estimate that drafting an initial state comprehensive quality strategy would take 70 hr at $53.32/hr for a business operations specialist to develop the proposed strategy, 2 hr at $29.92/hr for an office and administrative support worker to publicize the strategy, 15 hr at $53.32/hr for a business operations specialist to review and incorporate public comments into the strategy, and 1 hr at $29.92/hr for an office and administrative support worker to submit the initial quality strategy to CMS. We also estimate that 19 states would draft an initial comprehensive quality strategy (as the other 37 states already have an initial quality strategy). In aggregate, we estimate a one-time burden of **1,672 hr** (19 states x 88 hr) and **$87,817.24** [19 states x ((85 hr x $53.32/hr) + (3 hr x $29.92/hr))] for states to develop initial comprehensive quality strategies and submit them to CMS.

Section 431.504 State comprehensive quality strategy development, evaluation, and revision

This section describes the processes states would use for the development, evaluation, and revisions of a state comprehensive quality strategy, including state review and revision of the comprehensive quality strategy at least once every three years.

Section 431.504(a) would have states engage the public in the development of the

comprehensive quality strategy. The burden associated with this process is captured in §431.502 for the initial comprehensive quality strategy.

In accordance with proposed section 431.504(b), states would review and revise their comprehensive quality strategies as needed, but no less frequently than once every three years. While the 37 states that contract with MCOs and/or PIHPs currently revise their quality strategies periodically, approximately half of those states (18) revise their quality strategies less frequently that proposed.

We estimate a burden for the revision of a comprehensive quality strategy of, once every three years, 25 hr at $53.32/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at $29.92/hr for an office and administrative support worker to publicize the strategy, 5 hr at $53.32/hr for a business operations specialist to review and incorporate public comments, and 1 hr at $29.92/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of **198 hr** [(18 states x (33 hr) / 3 years] and **$10,136.16** [(18 states x ((30 hr x $53.32/hr) + (3 hr x $29.92/hr))) / 3 years].

The revision of a comprehensive quality strategy would be a new process for the 19 states that do not currently contract with MCOs and/or PIHPs. We estimate that those states would need 0.5 hr at $53.32/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate a one-time state burden of **9.5 hr** (19 states x 0.5 hr) and **$506.54** (9.5 hr x $53.32/hr) to update policies and procedures.

We assume that it will be less burdensome to revise an existing comprehensive quality strategy than to draft an initial strategy. Therefore, we estimate a burden for the comprehensive quality strategy revision process, once every three years, of 25 hr at $53.32/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at $29.92/hr for an office and administrative support worker to publicize the strategy, 5 hr at $53.32/hr for a business operations specialist to review and incorporate public comments, and 1 hr at $29.92/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of **209 hr** [(19 states x (33 hr) / 3 years] and **$10,699.28** [(19 states x ((30 hr x $53.32/hr) + (3 hr x $29.92/hr))) / 3 years].

Of the 37 states that contract with MCOs and/or PIHPs, we estimate that 10 states already have a comprehensive quality strategy. This could be due to a variety of reasons, such as the special terms and conditions of a section 1115 demonstration or in response to SHO Letter #13-007. The remaining 27 states would, at their next revision, transition from a quality strategy to a comprehensive quality strategy. We estimate that this would pose a burden of 10 hr at $53.32/hr for a business operations specialist at the next revision. In aggregate, we estimate a one-time state burden of **270 hr** (27 states x 10 hr) and **$14,396.40** (270 hr x $53.32/hr).

We propose in section 431.504(b)(1) that the review of the comprehensive quality strategy

would include an effectiveness evaluation conducted within the previous three years. We estimate the burden of this evaluation at 40 hr at $53.32/hr for a business operations specialist once every three years for all 56 states. The currently approved burden estimates that creating and submitting an implementation and effectiveness report to CMS for the 37 states with MCOs and/or PIHPs takes 40 hr per state once every three years. In its place, the review of the comprehensive quality strategy (including the effectiveness evaluation) would apply to the 56 states but the burden increase would apply to the remaining 19 states. In aggregate, we estimate an ongoing annualized burden of **253.3 hr** [(19 states x 40 hr) / 3 years] and **$13,505.96** (253.3 hr x $53.32/hr) to evaluate the effectiveness of a comprehensive quality strategy.

States would post the effectiveness evaluation on the state's Medicaid website under proposed section 431.504(b)(2). While this standard is subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned standards would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice.

As described in section 431.504(c), states would submit to CMS a copy of the initial comprehensive quality strategy and any subsequent revisions. The burden associated with this standard has been captured in §§431.502(a) (initial strategy) and 431.504(b) (revision of strategy). As this would be a new standard for the 19 states that do not currently contract with MCOs and/or PIHPs, we believe that these states would need to modify their policies and procedures to incorporate this action. We estimate a burden of 0.5 hr $53.32/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of **9.5 hr** (19 states x 0.5 hr) and **$506.54** (9.5 hr x $53.32/hr).

Finally, section 431.504(d) would have states post the final comprehensive quality strategy to their Medicaid websites. While this standard is subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned standards would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice.

<u>CQR Burden Estimate Summary</u>

There is no private sector burden associated with the comprehensive quality strategy. The overall annualized burden for the public sector for the comprehensive quality strategy is **1,313 hr** and **$68,750.31** for the 56 states and territories.

| Section in Title 42 of the CFR | Respondents | Responses | Time per Response (hr) | Total Hours | Labor Rate ($/hr) | Cost per Response ($) | Total Cost | Frequency | Annualized Hours* |
|---|---|---|---|---|---|---|---|---|---|

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 431.502(a) Initial CQS | 19 | 19 | 70 | 1330 | 53.32 | 3,732.40 | 70,915.60 | once | 443 |
| 431.502(a) Initial CQS | 19 | 19 | 2 | 38 | 29.92 | 59.84 | 1,136.96 | once | 13 |
| 431.502(a) Initial CQS | 19 | 19 | 15 | 285 | 53.32 | 799.80 | 15,196.20 | once | 95 |
| 431.502(a) Initial CQS | 19 | 19 | 1 | 19 | 29.92 | 29.92 | 568.48 | once | 6 |
| 431.504(b) Revise CQS | 18 | 18 | 25 | 150 | 53.32 | 1,333.00 | 7,998.00 | annual | 150 |
| 431.504(b) Revise CQS | 18 | 18 | 2 | 12 | 29.92 | 59.84 | 359.04 | annual | 12 |
| 431.504(b) Revise CQS | 18 | 18 | 5 | 30 | 53.32 | 266.60 | 1,599.60 | annual | 30 |
| 431.504(b) Revise CQS | 18 | 18 | 1 | 6 | 29.92 | 29.92 | 179.52 | annual | 6 |
| 431.504(b) Update Policies | 19 | 19 | 0.5 | 10 | 53.32 | 26.66 | 506.54 | once | 3 |
| 431.504(b) Revise CQS | 19 | 19 | 25 | 158 | 53.32 | 1,333.00 | 8,442.33 | annual | 158 |
| 431.504(b) Revise CQS | 19 | 19 | 2 | 13 | 29.92 | 59.84 | 378.99 | annual | 13 |
| 431.504(b) Revise CQS | 19 | 19 | 5 | 32 | 53.32 | 266.60 | 1,688.47 | annual | 32 |
| 431.504(b) Revise CQS | 19 | 19 | 1 | 6 | 29.92 | 29.92 | 189.49 | annual | 6 |
| 431.504(b) Revise QS to CQS | 27 | 27 | 10 | 270 | 53.32 | 533.20 | 14,396.40 | once | 90 |
| 431.504(b) (1) Evaluate CQS | 19 | 19 | 40 | 253 | 53.32 | 2,132.80 | 13,505.96 | annual | 253 |
| 431.504(c) Revise Policies | 19 | 19 | 0.5 | 10 | 53.32 | 26.66 | 506.54 | once | 3 |
| **TOTAL** | | | | | | | | | 1,313 |

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The costs associated with CQS are considered to be Medicaid administrative costs, and are therefore eligible for the 50 percent federal financial participation (FFP) matching rate. Therefore, of the estimated $68,750.31 total computable annualized costs, the Federal share is $34,375.16.

15. Changes to Burden

The comprehensive quality strategy is a new requirement for states; the associated burden is new and represents an increase due to a program change (issuing of new regulations).

16. Publication/Tabulation Dates

States will post current comprehensive quality strategies (CQS) on their websites. CMS will maintain a list of hyperlinks to current state CQS on Medicaid.gov. States will be required to review and revise their CQS at least once every three years; this process will include an effectiveness evaluation of the CQS, the results of which must be published on the state's website. CMS will review CQS submitted to the agency by states as a part of its normal oversight activities for the Medicaid program.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

**B. Collections of Information Employing Statistical Methods**

A statistical analysis of the collected information is not applicable.