

Supporting Statement – Part A
Medicaid Quality Assessment and Performance Improvement Programs,
State Review of Accreditation Status, Medicaid Managed Care Quality Rating System, and
Quality Strategy (QS) and Supporting Regulations in
§§438.310, 438.330, 438.332, 438.334, and 438.340
CMS-10553, OMB 0938-1281

Background

On May 6, 2016, CMS published a final rule (RIN 0938-AS25, CMS-2390-F) to modernize Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems (see 81 FR 27498).

This information collection request represents an extension of our currently approved information collection request. We are not proposing changes to any of our requirements or burden estimates. We are, however, proposing to adjust our cost estimates based on current BLS wage figures.

A. Justification

1. Need and Legal Basis (Social Security Act)

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.

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 managed care programs. This information may assist states in comparing the outcomes of quality improvement efforts 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 on their Medicaid websites reviews of the accreditation status of all managed care plans, their managed care plan quality ratings under the Medicaid and CHIP Quality Rating System, and final quality strategies including effectiveness evaluations of their strategies. 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 quality strategies and applications for alternative quality rating systems to CMS for review via email. No signature, electronic or written, is required for these documents.

4. Duplication of Efforts

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

5. Small Businesses

We estimate that some prepaid ambulatory health plans (PAHPs) and some primary care case management entities (PCCM entities) are likely to be small entities. We estimate that most managed care organizations (MCOs) and prepaid inpatient health plans (PIHPs) are not small entities. According to the Small Business Administration (SBA) and the Table of Small Business Size Standards, small entities include small businesses in the health care sector that are direct health and medical insurance carriers with average annual receipts of less than \$38.5 million and offices of physicians or health practitioners with average annual receipts of less than \$11 million.

We estimate that there are 335 MCOs, 176 PIHPs, 41 PAHPs, and 9 PCCM entities participating in the Medicaid managed care program. We believe that only a few of these entities qualify as small entities. Research on publicly available records for the entities allowed us to determine the approximate counts presented. Specifically, we believe that 10 to 20 PAHPs and 2 to 5 PCCM entities are likely to be small entities. We believe that the remaining MCOs and PIHPs have average annual receipts from Medicaid and CHIP contracts and other business interests in excess of \$38.5 million. In analyzing the scope of the impact of these regulations on small entities, we examined the United States Census Bureau's Statistics of U.S. Businesses for 2012. According to the 2012 data, there are 4,506 direct health and medical insurance issuers with less than 20 employees and 156,408 offices of physicians or health practitioners with less than 20 employees. We have no reason to believe that these estimates have significantly changed since then and therefore believe that we are impacting less than 1 percent of the small entities that we have identified.

The primary impact on small entities included in this collection will be adding PAHPs and PCCM entities to the QAPI program standards in §438.330. We do not believe that the remaining impacts or burdens of the provisions of this collection are great on the small entities that we have identified.

The estimated costs associated with the impacts on small entities listed above are primarily attributable to application of the QAPI program standards in §438.330 to PAHPs and PCCM entities. The application of the QAPI requirements to both PAHPs and PCCM entities accounts for approximately \$69,316.00 of the cumulative \$4.5 million estimated annual impact of the entire final rule on the 41 PAHPs and 9 PCCM entities (of which we estimate 10 to 20 PAHPs and 2 to 5 PCCM entities are likely to be small entities). The total estimated annual burden per PAHP is less than \$0.1 million, or less than 1 percent of the \$38.5 million threshold. The total estimated annual burden per PCCM entity is less than \$0.1 million, or less than 1 percent of the \$11 million threshold.

These small entities must meet certain standards as identified in the provisions of the May 6, 2016 final rule; however, we continue to believe these are consistent with the nature of their business in contracting with state governments for the provision of services to Medicaid and CHIP managed care enrollees. Moreover, when we invited comment in the proposed rule on our analysis of the impact on small entities, we received no comments. Because we have no reason to believe the estimates would have changed significantly since then, we have determined that these regulatory requirements will not have a significant economic impact on a substantial number of small entities.

6. Less Frequent Collection

States must review and revise the managed care quality strategy 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 quality strategy is a tool to help states drive quality improvement, and as such should not be allowed to stagnate.

States must at least annually post a quality rating for each MCO, PIHP and PAHP for Medicaid managed care enrollees to use in making informed choices about their managed care plan. If this were to occur less frequently, enrollees would not have current quality information when choosing a health plan, either for the first time or during the annual open- enrollment period.

7. Special Circumstances

There are no special circumstances. More specifically, this information collection does not do any of the following:

- Require respondents to report information to the agency more often than quarterly;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Require the use of a statistical data classification that has not been reviewed and approved by OMB;
- 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

-Require 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.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on March 20, 2019 (84 FR 10316). We did not receive any comments.

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 Quality Strategies on their websites, where they must also post the findings of the Quality Strategy effectiveness evaluations conducted at least once every three years.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

This section describes the requirements and burden for the Medicaid Quality Assessment and Performance Improvement Programs, State Review of Accreditation Status, Medicaid Managed Care Quality Rating System, and Quality Strategy (QS). We estimate 561 MCOs, PIHPs, and PAHPs, and PCCM entities for the private sector and 42 state governments.

12.1 *Wage Estimates*

To develop burden estimates, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Industry-Specific Occupational Employment and Wage Estimates. In this regard, the following table presents the median 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 Benefits and Overhead (at 100%) (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialist	13-1000	35.52	35.52	71.04

Computer Programmer	15-1131	43.07	43.07	86.14
General and Operations Mgr	11-1021	59.56	59.56	119.12
Office and Administrative Support Worker	43-9000	17.28	17.28	34.56

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, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2 Requirements and Burden Estimates

Section 438.310 Basis, Scope, and Applicability

Section 438.310(c)(2) applies §438.330(b)(3), (c), and (e), §438.340(e) and §438.350 to states whose contracts with PCCM entities include shared savings, incentive payments, or other financial reward for the PCCM entity for improved quality outcomes. This will affect a specific subset of approximately 9 PCCM entities and 5 states.

We estimate a one-time state burden of 2 hr at \$71.04/hr for a business operations specialist to address the performance assessment of PCCM entities described in §438.310(c)(2) by revising a state's policies and procedures. In aggregate, we estimate 10 hr (5 states x 2 hr) and \$710.40 (10 hr x \$71.04/hr), annualized to **3.3 hr** and **\$236.80** (Estimate 12.1). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.330 Quality Assessment and Performance Improvement Program

Section 438.330(a)(2) specifies the process CMS will use if it elects to specify a common set of national QAPI performance measures and PIP topics, which will include a public notice and comment process. Assuming that we do use this process to identify QAPI performance measures and PIP topics at least once every 3 years, the burden for states will be altered.

Some may experience a decrease in the time spent selecting performance measures and PIP topics while others might experience a slight increase in the time needed for computer programming of their MMIS or Transformed-MMIS to account for the specified performance measures and PIP topics.

We estimate a state burden of 10 hr (every 3 years) at \$86.14/hr for a computer programmer to make the MMIS/T-MSIS programming changes. In aggregate, we estimate an annualized burden of **133.3 hr** [(40 states x 10 hr) / 3 years] and **\$11,485.33** (133.3 hr x \$86.14/hr). We cannot estimate the amount of possible decrease in burden as we have no way to know the average amount of time a state expended on selecting performance measures or PIP topics and how this might change based on this revision (Estimate 12.2).

Section 438.330(a)(2) also will allow states to apply for an exemption from the CMS- specified QAPI performance measures and PIP topics if they are identified under §438.330(a)(2). While we have no data on how many states will take advantage of this option, given that the performance measures and PIP topics under §438.330(a)(2) will be identified through a public notice and comment process, we estimate that approximately 11 states will ask for an exemption every 3 years. We estimate a state burden of 1 hr (every 3 years) at \$71.04/hr for a business operations specialist to comply with the exemption process. In aggregate, we estimate an annualized burden of **3.7 hr** [(11 states x 1 hr)/3 years] and **\$260.48** (3.7 hr x \$71.04/hr) (Estimate 12.3).

Section 438.330(a)(3) identifies the regulatory components of §438.330 that apply to the QAPI of a PCCM entity described in §438.310(c)(2). The burden associated with these regulatory components in regards to PCCM entities is described in §§438.330(b)(3), (c), and (e) below.

Section 438.330(b)(3) clarifies that MCOs, PIHPs, and PAHPs will have an approach to evaluate and address findings regarding the underutilization and overutilization of services. Because utilization review in managed care has become commonplace in the private, Medicare, and Medicaid settings, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or PAHPs. However, in accordance with §438.310(c)(2), PCCM entities (we estimate there are 9 total) will now be subject to this operational component.

We recognize that PCCM entities may not currently have in place mechanisms to assess and address underutilization and overutilization of services in accordance with §438.330(b)(3).

We estimate a one-time private sector burden of 10 hr at \$71.04/hr for a business operations specialist to establish the policies and procedures. In aggregate, we estimate 90 hr (9 PCCM entities x 10 hr) and **\$6,139.80** (90 hr x \$71.04/hr), annualized to **30 hr** and **\$2,131.20**, for the establishment of policies and procedures (Estimate 12.4). We are annualizing the one-time burden since we do not anticipate any additional development burden after the 3-year approval period expires.

We also estimate an ongoing annual burden of 10 hr to evaluate and address the findings. In aggregate, we estimate **90 hr** (9 PCCM entities x 10 hr) and **\$6,393.60** (90 hr x \$71.04/hr) for program maintenance (Estimate 12.5).

Section 438.330(c) addresses QAPI performance measurement. Section 438.330(c)(1) requires that the state identify standard performance measures for their managed care plans, including LTSS measures if appropriate. These must include any performance measures specified by CMS under §438.330(a)(2). We believe that it is standard practice for states to identify performance measures for their contracted managed care plans; therefore there is no burden associated with this paragraph.

Section 438.330(c)(2) requires each MCO, PIHP, PAHP, and PCCM entity (described in §438.310(c)(2)) to annually measure its performance using the standard measures specified by the state in §438.330(c)(1) and to report on its performance to the state. We assume that each of the 335 MCOs and 176 PIHPs will report on three performance measures to the state. The use of

performance measures is commonplace in private, Medicare, and Medicaid managed care markets; therefore we believe that MCOs and PIHPs already collect performance measures.

For MCOs (335) and PIHPs (176), we estimate an annual private sector burden of 0.1 hr at \$71.04/hr for a business operations specialist to report on a single performance measure to the state. In aggregate, we estimate **153.3 hr** (511 MCOs and PIHPs x 3 performance measures x 0.1 hr) and **\$10,890.43** (153.3 hr x \$71.04/hr) (Estimate 12.6).

We recognize that PAHPs and PCCM entities (described in §438.310(c)(2)) may not currently engage in performance measurement as described in §438.330(c)(2). We estimate that each PCCM entity and each PAHP will report to the state on 3 performance measures annually.

For the 41 PAHPs and 9 PCCM entities, we estimate an annual private sector burden of 4 hr (per measure) at \$71.04/hr for a business operations specialist to collect, calculate, and submit each performance measure to the state. In aggregate, we estimate **600 hr** (50 PAHPs and PCCMs x 3 performance measures x 4 hr) and **\$42,624.00** (600 hr x \$71.04/hr) (Estimate 12.7).

Section 438.330(c)(2) also requires each MCO, PIHP, PAHP, and PCCM entity (described in §438.310(c)(2)) providing long-term services and supports to annually measure its performance using the standard measures specified by the state in §438.330(c)(1)(ii) and to report on its performance to the state. Section 438.330(c)(1)(ii) requires states to identify standard performance measures in two LTSS-specific categories for managed care plans that provide LTSS. Assuming that each of the 179 MLTSS plans will report on at least one measure per category and a burden of 4 hr (per measure) at \$71.04/hr for a business operations specialist to collect, calculate, and submit each LTSS performance measure to the state, we estimate an aggregated annual private sector burden of **1,432 hr** (179 MLTSS plans x 2 performance measures x 4 hr) and **\$101,729.28** (1,432 hr x \$71.04/hr) (Estimate 12.8).

Under §438.330(d)(1) through (3), states must ensure that each MCO, PIHP, and PAHP has an ongoing program of PIPs, designed to achieve sustainable improvement, which the managed care plan will report on to the state as requested, but at least once per year. We assume that each MCO and PIHP will conduct at least 3 PIPs in any given year. We further expect that states would request the status and results of each entity's PIPs annually. The currently approved burden under this control number estimates that each of the 539 MCOs and PIHPs conducts 3 PIPs, for a burden of 12,936 hr (539 MCOs and PIHPs x 3 PIPs x 8 hr). However, this figure overestimates the number of MCOs and PIHPs. Therefore, we estimate an annual private sector burden of 8 hr at \$71.04/hr for a business operations specialist to report on each PIP. In aggregate, we estimate **12,264 hr** (511 MCOs and PIHPs x 8 hr x 3 PIPs) and **\$871,234.56** (12,264 hr x \$71.04/hr) (Estimate 12.9).

We assume that each PAHP will conduct at least one PIP each year, and that states will request the status and results of each PAHP's PIP annually. We estimate a one-time private sector burden of 2 hr at \$71.04/hr for a business operations specialist to develop policies and procedures. In aggregate, we estimate **82 hr** (41 PAHPs x 2 hr) and **\$5,825.28** (82 hr x \$71.04/hr), annualized to **27.3 hr** and **\$1,941.76** (Estimate 12.10). We are annualizing the one-time burden since we do not anticipate any additional burden after the 3-year approval period expires.

We also estimate an annual private sector burden of 8 hr to prepare a PIP report. In aggregate, we estimate **328 hr** (41 PAHPs x 1 PIP x 8 hr) and **\$23,301.12** (328 hr x \$71.04/hr) (Estimate 12.11).

Section 438.330(e)(1) requires the state to review the impact and effectiveness of each MCO's, PIHPs, and PAHP's QAPI at least annually. States must also review the QAPI of each PCCM entity (described in §438.310(c)(2)). We estimate an annual state burden of 15 hr at \$71.04/hr for a business operations specialist to assess the performance of a single PCCM entity. In aggregate, we estimate **135 hours** (9 PCCM entities x 15 hr) and **\$9,590.40** (135 hr x \$71.04/hr) (Estimate 12.12).

Under section 438.330(e)(1)(ii), states will include outcomes and trended results of each MCO, PIHP, and PAHP's PIPs in the state's annual review of quality assessment and performance improvement programs. We estimate a one-time state burden of 0.5 hr at \$71.04/hr for a business operations specialist to modify policies and procedures for the 40 states with MCOs, PIHPs and PAHPs. In aggregate, we estimate **20 hr** (40 states x 0.5 hr) and **\$1,420.80** (20 hr x \$71.04/hr), annualized to **6.7 hr** and **\$473.60** (Estimate 12.13). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

We also estimate an annual state burden of 1 hr to conduct the additional annual review of the outcomes and trended results for each of the 552 MCOs, PIHPs, and PAHPs (335 MCOs, 176 PIHPs, 41 PAHPs). In aggregate, we estimate **552 hr** (552 MCOs, PIHPs, and PAHPs x 1 hr) and **\$39,214.08** (552 hr x \$71.04/hr) (Estimate 12.14).

Section 438.330(e)(1)(iii) is a new program component, related to §438.330(b)(5), which will require a state (in its annual review) to assess the results of any efforts to support state goals to promote community integration of beneficiaries using LTSS in place at the MCO, PIHP, or PAHP. We estimate that the 16 states with MLTSS plans will need to modify their policies and procedures regarding the annual review of quality assessment and performance improvement programs in their managed care entities. We estimate a one-time state burden of 0.5 hr at \$71.04/hr for a business operations specialist to modify the state's policies and procedures. In aggregate, we estimate 8 hr (16 states x 0.5 hr) and \$568.32 (8 hr x \$71.04/hr), annualized to **2.7 hr** and **\$189.44** (Estimate 12.15). We are annualizing the one-time burden since we do not anticipate any additional burden after the 3-year approval period expires.

We also estimate an annual burden of 1 hr for the assessment of rebalancing efforts of each of the 179 MLTSS plans. In aggregate, we estimate **179 hr** (179 MLTSS plans x 1 hr) and **\$12,716.16** (179 hr x \$71.04/hr) for the assessment (Estimate 12.16).

Section 438.332 State Review of the Accreditation Status of MCOs, PIHPs, and PAHPs

Under §438.332(a), states must confirm the accreditation status of contracted MCOs, PIHPs, and PAHPs once a year. We estimate an annual state burden of 0.25 hr at \$71.04/hr for a business operations specialist to review the accreditation status of each of the estimated 552 MCOs,

PIHPs, and PAHPs. In aggregate, we estimate an annual burden of **138 hr** (0.25 hr x 552 MCOs, PIHPs, and PAHPs) and **\$9,803.52** (138 hr x \$71.04/hr) (Estimate 12.17).

Section 438.332(b) describes the information MCOs, PIHPs, and PAHPs must authorize the private accrediting entity to release to the state regarding the plan's accreditation status. We believe that states will need to amend their MCO, PIHP, and PAHP contracts to reflect this requirement, and estimate a one-time burden of 0.25 hr per contract amendment. In aggregate, we estimate a one-time burden of **138 hr** (0.25 hr x 552 MCOs, PIHPs, and PAHPs) and **\$9,803.52** (138 hr x \$71.04/hr), annualized to **46 hr** and **\$3,267.84** (Estimate 12.18). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Under §438.332(c), states will document the accreditation status of each contracted MCO, PIHP, and PAHP on the state's website, and will update this information at least annually. The burden is included in §438.10.

Section 438.334 Medicaid Managed Care Quality Rating System

Section 438.334(a) requires each state that contracts with an MCO, PIHP or PAHP to adopt a Medicaid managed care quality rating system to generate plan ratings annually. States must either adopt the quality rating system developed by CMS in accordance with §438.334(b) or an alternative Medicaid managed care quality rating system in accordance with §438.334(c).

We assume each state will create a single Medicaid managed care quality rating system for all of the state's contracted MCOs, PIHPs, and PAHPs. We are aware of 8 states that currently operate a quality rating system or quality report card for the state's Medicaid managed care program; we assume that these states may want to continue to use their existing system given the investments already made in these systems. We also assume that a couple of states may determine that a state-specific approach is most suitable for them. Therefore, we estimate that of the 40 states that contract with MCOs, PIHPs, and PAHPs, 30 states will elect to adopt the Medicaid managed care quality rating system developed by CMS in accordance with §438.334(b), while the remainder (10 states) will elect to utilize an alternative Medicaid managed care quality rating system in accordance with §438.334(c). We further estimate that 75 percent (414) of MCOs, PIHPs, and PAHPs operate in these 30 states. We assume that, given the robust public engagement process CMS will use to develop the MMC QRS in accordance with §438.334(b), states electing to adopt the CMS-developed MMC QRS will not need to conduct additional public engagement and will require less time to develop their MMC QRS as compared to states which elect to adopt an alternative MMC QRS consistent with §438.334(c).

Therefore, for states adopting the CMS-developed MMC QRS under §438.334(b), we estimate the state burden for the development and implementation of the MMC QRS as 200 hr at \$71.04/hr for a business operations specialist, 100 hr at \$86.14/hr for a computer programmer, and 30 hr at \$119.12/hr for a general and operations manager. In aggregate, we estimate a one-time state burden of **9,900 hr** (30 states x 330 hr) and **\$791,868.00** [30 states x ((200 hr x \$71.04/hr) + (100 hr x \$86.14/hr) + (30 hr x \$119.12/hr)], annualized to **3,300 hr** and **\$263,956.00** for the development of states' Medicaid managed care quality rating system consistent with 438.334(b) (Estimate 12.19).

We are annualizing the one-time burden since we do not anticipate any additional burden after the 3-year approval period expires.

The burden is more variable for states seeking CMS approval for the adoption of an alternative MMC QRS per §438.334(c). A state may submit an existing MMC QRS, may submit a modified version of an existing MMC QRS, or may develop a new MMC QRS. We assume that the burden for each of these options will vary by state and will be lowest for states that submit an existing MMC QRS for CMS approval and highest for states that develop a new MMC QRS. For the purposes of this estimate, we assume a standard burden across all states for the development of an alternative MMC QRS. We believe that the average alternative MMC QRS burden will exceed the burden to adopt the CMS-developed MMC QRS, and will require public engagement by the state. Therefore, we estimate the average state burden for the development and implementation of an alternative MMC QRS as 800 hr at \$71.04/hr for a business operations specialist, 400 hr at \$86.14/hr for a computer programmer, and 120 hr at \$119.12/hr for a general and operations manager. We estimate an additional 20 hr at \$34.56/hr for an office and administrative support worker for the public engagement process and an additional 50 hr at \$71.04/hr for a business operations specialist to review and incorporate public feedback. In aggregate, we estimate a one-time state burden of **13,900 hr** (10 states x 1,390 hr) and **\$1,098,256.00** [10 states x ((800 hr x \$71.04/hr) + (400 hr x \$86.14/hr) + (120 hr x \$119.12/hr) + (20 hr x \$34.56/hr) + (50 hr x \$71.04/hr))], annualized to **4,633.3 hr** and **\$366,085.33**, for the development of states' alternative Medicaid managed care quality rating system consistent with §438.334(c) (Estimate 12.20). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

To elect the option under §438.334(c) to use an alternative MMC QRS, a state will submit a request to CMS and must receive written CMS approval. We estimate a one-time state burden of 20 hr at \$71.04/hr for a business operations specialist to seek and receive approval from CMS for the state's Medicaid managed care alternative quality rating system. In aggregate, we estimate 200 hr (10 states x 20 hr) and **\$14,208.00** (200 hr x \$71.04/hr), annualized to **66.7 hr** and **\$4,736.00** (Estimate 12.21). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.334(c)(3) outlines the process for a state to make changes to an approved alternative MMC QRS. We estimate that it will require 5 hr at \$34.56/hr for an office and administrative support worker and 25 hr at \$71.04/hr for a business operations specialist to complete the public comment process, and an additional 5 hr at \$71.04/hr from a business operations specialist to seek and receive approval from CMS for the change. While we have no data to estimate how frequently a state may elect to alter an approved alternative MMC QRS, we estimate that CMS will revise the MMC QRS under §438.334(b) on average approximately once every three years. We assume that states will revise their alternative QRS on a similar frequency (once every three years) to ensure that the alternative QRS continues to yield substantially comparable information regarding MCO, PIHP, and PAHP performance, and apply this assumption here. Therefore, we estimate an aggregate annual burden of **116.7 hr** [(10 states x 35 hr) / 3 years] and **\$7,680.00** [(10 states x ((5 hr x \$34.56/hr) + (30 x \$71.04/hr))) / 3 years] (Estimate 12.22).

Under §438.334(d), each state will collect information from its MCOs, PIHPs, and PAHPs to

calculate and then issue a quality rating each year. We expect that states will rely on information and data already provided to them by their MCOs, PIHPs, and PAHPs; therefore, we do not expect this data collection to pose an additional burden on the private sector.

However, each year states will rate each MCO, PIHP, or PAHP with which they contract. We estimate 40 hr at \$71.04/hr for a business operations specialist for a state to rate a MCO, PIHP, or PAHP. We believe this burden will be similar for states regardless of if they adopt the CMS-developed MMC QRS consistent with §438.334(b) or the alternative MMC QRS consistent with §438.334(c). In aggregate, we estimate an annual state burden of **22,080 hr** (552 MCOs, PIHPs, and PAHPs x 40 hr) and **\$1,568,563.20** (22,080 hr x \$71.04/hr) (Estimate 12.23).

Section 438.334(e) requires states to prominently display quality rating information for plans on the state website described in §438.10. The burden associated with this process is captured in §438.10.

Section 438.340 Managed Care State Quality Strategy

Previous regulations at §438.204(b)(2) described a quality strategy element, specifically that states contracting with MCOs and/or PIHPs identify the race, ethnicity, and primary language spoken of each Medicaid enrollee, and report this information to MCOs and PIHPs upon enrollment into a plan. While we had inadvertently proposed to delete this quality strategy element, under the final rule we are retaining this element and incorporating it into §438.340(b)(6), which requires states to include a plan to identify, evaluate, and reduce health disparities in the managed care quality strategy. Therefore, under the final rule there is a burden on states to provide the identified demographic data (age, race, ethnicity, sex, primary language, and disability status) to MCOs, PIHPs, and PAHPs. The burden associated with previous regulations at §438.204(b)(2) was estimated at 80 hr per state (for 15 states) to collect and report on the race, ethnicity, and primary language spoken, for an aggregate burden of 1,200 hr (15 states x 80 hr) (note that the previous burden did not include an associated hourly wage). We are replacing that burden with a new estimate to account for the additional demographic information which states must provide to MCOs, PIHPs, and PAHPs under §438.340(b)(6). Assuming that the estimated 40 states that contract with MCOs, 12 PIHPs, and PAHPs provide demographic information electronically to these plans once each year, we estimate a burden for the reporting of these six demographic factors to MCOs, PIHPs, and PAHPs of 130 hr, half at \$71.04/hr for a business operations analyst and half at \$34.56/hr for an office and administrative support worker. In aggregate, we estimate an ongoing annual state burden of **5,200 hr** (130 hr x 40 states) and **\$274,560.00** [40 states x ((65 hr x \$71.04/hr) + (65 hr x \$34.56/hr))] (Estimate 12.24).

In accordance with §438.340(c)(2), states will review and revise their quality strategies as needed, but no less frequently than once every 3 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 than proposed. We estimate a burden for the revision of a quality strategy of, once every 3 years, 25 hr at \$71.04/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at \$34.56/hr for an office and administrative support worker to publicize the strategy, 5 hr at \$71.04/hr for a business operations specialist to review and incorporate public comments, and 1 hr at \$34.56/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we

estimate an ongoing annual state burden of **198 hr** [(18 states x 33 hr) / 3 years] and **\$12,821.76**[(18 states x ((30 hr x \$71.04/hr) + (3 hr x \$34.56/hr))) / 3 years] (Estimate 12.25).

The revision of a quality strategy will be a new process for the estimated three states with only PAHPs and the estimated two states with only PCCM entities. We estimate that those states need 0.5 hr at \$71.04/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate a one-time state burden of **2.5 hr** (5 states x 0.5 hr) and **\$177.60** (2.5 hr x \$71.04/hr), annualized to **0.8 hr** and **\$59.20**, to update policies and procedures (Estimate 12.26). We are annualizing the one-time burden since we do not anticipate any additional development burden after the 3-year approval period expires.

We assume that it will be less burdensome to revise an existing quality strategy than to draft an initial strategy. Therefore, we estimate an ongoing burden for the quality strategy revision process for states with only PAHPs and PCCM entities, once every 3 years, of 25 hr at \$71.04/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at \$34.56/hr for an office and administrative support worker to publicize the strategy, 5 hr at \$71.04/hr for a business operations specialist to review and incorporate public comments, and 1 hr at \$34.56/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annual state burden of **55 hr** [(5 states x 33 hr) / 3 years] and **\$3,724.80** [(5 states x ((30 hr x \$71.04/hr) + (3 hr x \$34.56/hr))) / 3 years] (Estimate 12.27).

Consistent with §438.340(c)(2), the review of the quality strategy will include an effectiveness evaluation conducted within the previous 3 years. We estimate the burden of this evaluation at 40 hr at \$71.04/hr for a business operations specialist once every 3 years for all 42 states that contract with MCOs, PIHPs, PAHPs, and/or PCCM entities (described in §438.310(c)(2)). In aggregate, we estimate an ongoing burden of **560 hr** [(42 states x 40 hr) / 3 years] at a cost of **\$39,782.40** (560 hr x \$71.04/hr) (Estimate 12.28). The currently approved burden estimates for 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 3 years, for an annualized burden of 493.3 hr [(37 states x 40hr) / 3]; therefore, the only new burden is associated with the estimated 3 states with only PAHPs and the estimated 2 states with only PCCM entities. Therefore, we estimate a net ongoing annual burden of 66.7 hr [((42 states x 40 hr) – (37 states x 40 hr)) / 3 years] and **\$4,738.40** (66.7 hr x \$71.04/hr) to evaluate the effectiveness of a quality strategy.

Section §438.340(c)(2)(ii) requires states to post the managed care quality strategy effectiveness evaluation on the state's Medicaid website. We estimate that posting the quality strategy effectiveness evaluation online will require 0.25 hr at \$71.04 from a business operations specialist once every three years. In aggregate, we estimate an ongoing annual burden of **3.5 hr** [(42 states x 0.25 hr) / 3 years] and **\$248.64** (3.5 hr x \$71.04/hr) (Estimate 12.29).

As described in §438.340(c)(3), states will submit to CMS a copy of the initial quality strategy and any subsequent revisions. The burden associated with this standard has been incorporated into burden estimates for initial and revised quality strategies. As this will be a new standard for the estimated 3 states with only PAHPs and the estimated 2 states with only PCCM entities, we believe that these states will need to modify their policies and procedures to incorporate this action. We estimate a burden of 0.5 hr at \$71.04/hr for a business operations specialist. In aggregate, we

estimate a one-time state burden of 2.5 hr (5 states x 0.5 hr) and \$177.60 (2.5 hr x \$71.04/hr), annualized to **0.8 hr** and **\$59.20** (Estimate 12.30). We are annualizing the one-time burden since we do not anticipate any additional development burden after the 3-year approval period expires.

Section 438.340(d) requires states to post the final quality strategy to their Medicaid websites. We estimate that posting the final quality strategy online will require 0.25 hr at \$71.04 from a business operations specialist once every three years. In aggregate, we estimate an ongoing annual burden of **3.5 hr** [(42 states x 0.25 hr) / 3 years] and **\$248.64** (3.5 hr x \$71.04/hr) (Estimate 12.31).

12.3 Summary of Burden Estimates

Summary of Annual Burden Estimates: States

Response Type: R=reporting; TPD=third-party disclosure

Estimate #	CFR Section	# Respondents	# Responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total Cost (\$)	Frequency	Response Type	Annualized hours*	Annualized costs (\$)
12.1	438.310(c)(2) State PCCM Assessment	5	5	2	10	71.04	142.08	710.40	once	TPD	3.3	236.80
12.18	438.332(b) Amend MCO, PIHP, PAHP Contracts	40	552	0.25	138	71.04	17.76	9,803.52	once	TPD	46	3,267.84
12.24	438.340(b)(6) Report demographic data	40	40	130	5,200	varies	6,864.00	274,560.00	annual	TPD	5,200	274,560.00
12.29	438.340(c)(2)(ii) Post QS Effectiveness Evaluation Online	42	42	0.25	10.5	71.04	17.76	745.92	annual	TPD	3.5	248.64
12.31	438.340(d) Post Final QS Online	42	42	0.25	10.5	71.04	17.76	745.92	annual	TPD	3.5	248.64
	SUBTOTAL: Third-Party Disclosure	42	681	varies	5,369	varies	7,059.36	286,565.76	n/a	TPD	5,256.3	278,561.92
12.2	438.330(a)(2) State QAPI Programming	40	40	10	400	86.14	861.40	34,456.00	annual	R	133.3	11,485.33
12.3	438.330(a)(2) State QAPI Exemption	11	11	1	11	71.04	71.04	781.44	annual	R	3.7	260.48
12.12	438.330(e) Assess PCCMs	9	9	15	135	71.04	1,065.60	9,590.40	annual	R	135	9,590.40

Estimate #	CFR Section	# Respondents	# Responses	Burden per response (hours)	Total Annual Hour	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Response Type	Annualized hours*	Annualized costs (\$)
12.13	438.330(e)(1)(ii) Update State Policies	40	40	0.5	20	71.04	35.52	1,420.80	once	R	6.7	473.60
12.14	438.330(e)(1)(ii) State Review of Outcomes	40	552	1	552	71.04	71.04	39,214.08	annual	R	552	39,214.08
12.15	438.330(e)(1)(iii) Update State Policies	16	16	0.5	8	71.04	35.52	568.32	once	R	2.7	189.44
12.16	438.330(e)(1)(iii) State Assess LT SS	16	179	1	179	71.04	71.04	12,716.16	annual	R	179	12,716.16
12.17	438.332(a) Confirmation of Accreditation Status	40	552	0.25	138	71.04	17.76	9,803.52	annual	R	138	9,803.52
12.19	438.334(b) State Adopts CMS QRS	30	30	330	9,900	71.04	26,395.60	791,868.00	once	R	3,300	263,956.00
12.20	438.334(c) State Adopts Alternative QRS	10	10	1,390	13,900	varies	109,825.60	1,098,256.00	once	R	4,633.3	366,085.33
12.21	438.334(c) Obtain CMS Approval for Alternative QRS	10	10	20	200	71.04	1,420.80	14,208.00	once	R	66.7	4,736.00
12.22	438.334(c)(3) Amend Alternative QRS	10	10	35	350	varies	2,237.00	22,370.00	annual	R	116.7	7,680.00
12.23	438.334(d) Calculate and Issue Ratings	40	552	40	22,080	71.04	2,841.60	1,568,563.20	annual	R	22,080	1,568,563.20
12.25	438.340(c)(2) Revise QS MCO/PIHP States	18	18	33	594	varies	2,136.96	38,465.28	annual	R	198	12,821.76

Estimate #	CFR Section	# Respondents	# responses	Burden per response	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Response Type	Annualized hours*	Annualized costs (\$)
12.26	438.340(c)(2) Update Policies PAHP/PCCM States	5	5	0.5	2.5	71.04	35.52	177.60	once	R	0.8	59.20
12.27	438.340(c)(2) Revise QS PAHP/PCCM States	5	5	33	165	varies	2,234.88	11,174.40	annual	R	55	3,724.80
12.28	438.340(c)(2) QS Effectiveness Evaluation	42	42	40	1,680	71.04	2,841.60	119,347.20	annual	R	560	39,782.40
12.30	438.340(c)(3) Revise Policies PAHP/PCCM States	5	5	0.5	2.5	71.04	35.52	177.60	once	R	0.8	59.20
	<i>SUBTOTAL: Reporting</i>	42	2,086	Varies	50,317	Varies	152,234.00	3,733,158.00	n/a	R	32,161.7	2,351,200.91
	TOTAL	42	2,767	Varies	55,686	varies	159,293.36	4,059,723.76	n/a	n/a	37,418	2,629,762.83

Summary of Annual Burden Estimates: Private Sector

Response Type: R=reporting; TPD=third-party disclosure

Estimate #	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Response Type	Annualized hours*	Annualized costs (\$)
12.4	438.330(b)(3) Create PCCM Utilization Review Policies	9	9	10	90	71.04	710.40	6,393.60	once	TPD	30	2,131.20
12.10	438.330(d)(1)-(3) Create PAHP PIP Policies	41	41	2	82	71.04	142.08	5,825.28	once	TPD	27.3	1,941.76

Estimate #	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Response Type	Annualized hours*	Annualized costs (\$)
	<i>SUBTOTAL: Third-Party Disclosure</i>	50	50	varies	172	71.04	852.48	12,218.88	once	TPD	57.33	4,072.96
12.5	438.330(b)(3) Operate PCCM Utilization Review Policies	9	9	10	90	71.04	710.40	6,393.60	annual	R	90	6,393.60
12.6	438.330(c)(2) MCO/PIHP Performance Measures	511	1,533	0.1	153.3	71.04	7.10	10,890.43	annual	R	153.3	10,890.43
12.7	438.330(c)(2) PAHP/PCCM Performance Measures	50	150	4	600	71.04	284.16	42,624.00	annual	R	600	42,624.00
12.8	438.330(c)(2) MLT SS Performance Measures	179	358	4	1,432	71.04	284.16	101,729.28	annual	R	1,432	101,729.28
12.9	438.330(d)(1)-(3) MCO/PIHP PIPs	511	1,533	8	12,264	71.04	568.32	871,234.56	annual	R	12,264	871,234.56
12.11	438.330(d)(1)-(3) PAHP PIPs	41	41	8	328	71.04	568.32	23,301.12	annual	R	328	23,301.12
	<i>SUBTOTAL: Reporting</i>	511	3,624	varies	14,867.3	71.04	2,422.46	1,056,172.99	annual	R	14,867.3	1,056,172.99
	TOTAL	561	3,674	varies	15,039.3	71.04	3,274.94	1,068,391.87	n/a	n/a	14,924.6	1,060,245.95

12.4 Information Collection Instruments and Guidance/Instruction Documents

None.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

This collection involves both private sector (MCOs, PIHPs, PAHPs, and certain PCCM entities) and public sector (state government) costs associated with §§438.310, 438.320, 438.330, 438.332, 438.334 and 438.340.

Total annualized private sector costs are **\$1,060,245.95**. Consistent with the assumptions used for the private sector match rate in the final rule (RIN 0938-AS25, CMS-2390-F), we assume that the private sector will pass long costs to states through their capitation rates and estimate a weighted Federal match rate of 58.44 percent (weighted for enrollment). Therefore, the Federal share for annualized private sector costs is **\$619,607.73**.

The public sector costs associated with these provisions 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 **\$2,629,762.83** total computable annualized costs, the Federal share is **\$1,314,881.41**.

TOTAL \$1,934,489.15

15. Changes to Burden

Adjustments have been made to account for updated BLS wages. The adjustments add \$303,938 to our cost estimates, namely from \$3,386,071 (using May 2014 wages) to \$3,690,009 (using May 2018 wages).

16. Publication/Tabulation Dates

States must at least annually, make the accreditation status for each contracted MCO, PIHP, and PAHP available on the website required under §438.10(c)(3), including whether each MCO, PIHP, and PAHP has been accredited and, if applicable, the name of the accrediting entity, accreditation program, and accreditation level.

States must prominently display the annual quality rating given by the State to each MCO, PIHP, or PAHP on the website required under §438.10(c)(3). States must implement a quality rating system within 3 years of the date of a final notice published in the Federal Register.

States must post current quality strategies (QS), which include all of the elements required in §438.340(b) on their websites. CMS will maintain a list of hyperlinks to current state QS on Medicaid.gov. States are required to review and revise their QS at least once every three years; this process includes an effectiveness evaluation of the QS, the results of which must be published on the state's website. States must make the strategy available for public comment before submitting the strategy to CMS for review CMS will review QS submitted to the agency by states as a part of its normal oversight activities for the Medicaid program.

17. Expiration Date

We display the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.