Supporting Statement - Part A
External Quality Review (EQR) of Medicaid Managed Care, EQR Protocols, and Supporting Regulations in 42 CFR 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370
CMS-R-305, OMB 0938-0786

**Background**

A rule concerning external quality review (EQR) of Medicaid managed care organizations (MCOs) published on January 24, 2003 (68 FR 3586). The EQR regulation implemented (1) section 1932(c)(2) of the Social Security Act (the Act), which was enacted in section 4705(a) of the Balanced Budget Act of 1997 (BBA), and (2) section 1903(a)(3)(C)(ii) of the Act, which was enacted in section 4705(b) of the BBA. Under section 1932(c)(2) each contract between a state Medicaid agency (state agency) and an MCO must provide for an annual EQR of the quality outcomes, the timeliness of, and access to, the services for which the MCO is responsible under the contract. Section 1903(a)(3)(C) provides enhanced matching for these activities. The final rule was published on January 24, 2003; it expanded the application of the EQR provisions to prepaid inpatient health plans (PIHPs) and to other risk comprehensive contracts states have with organizations exempt from 1903(m), such as certain health insuring organizations (HIOs).

On May 6, 2016, CMS published a final rule (RIN 0938-AS25, CMS-2390-F) to modernize Medicaid managed care external quality review provisions and apply them to prepaid ambulatory health plans (PAHPs) and certain primary care case management entities (PCCM entities) whose contracts with states provide for quality incentives (see 81 FR 27498). This information collection request aligns our external quality activities with the provisions of the final rule.

*External Quality Review (EQR)*

The annual EQR is to be conducted by an independent entity (an external quality review organization, EQRO) that meets the qualifications set forth in these regulations. State agencies may use information about an MCO, PIHP, or PAHP, obtained through a Medicare or private accreditation review, in place of information generated through the EQR-related activities, if such activities would duplicate the activities under the Medicare or private accreditation review. Further, and consistent with BBA provisions, states may exempt certain MCOs from the annual EQR process.

The BBA provisions require that the results of the EQR (which are referred to as EQR technical reports) be made publicly available; CMS-2390-F requires states to post EQR technical reports on the state's website, in addition to providing the reports such parties as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, PAHP, or PCCM entity upon request. The BBA also authorizes the payment of enhanced Federal financial participation at the 75 percent rate for expenditures on EQR (including the production of EQR results) and EQR-related activities performed on MCOs when conducted by EQROs. EQR-related activities conducted on MCOs by entities other than an EQRO,

and EQR-related activities and EQR of non-MCOs, is eligible for a 50 percent match rate.

*EQR Activities and Protocols*

States that contract with MCOs, PIHPs, PAHPs, and certain PCCM entities to deliver Medicaid services would conduct an EQR of each plan each year. There are four mandatory EQR-related activities: validation of performance improvement projects; validation of performance measures; a compliance review once every three years; and, under CMS-2390-F, validation of network adequacy. There are six optional EQR-related activities, the data from which must be included in a state's EQR if the state elects to conduct the activity: validation of encounter data; administration or validation of consumer or provider surveys; calculation of additional performance measures; additional performance improvement projects; focus studies, and, under CMS-2390-F, assist with the quality rating of MCOs, PIHPs, and PAHPs. States, their contractors that are not MCOs, PIHPs, PAHPs, or PCCM entities, or EQROs must conduct the EQR-related activities either using the EQR protocols or using methods consistent with these protocols.

Through a competitive procurement, CMS awarded a contract to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to develop the original protocols for external quality review activities. A Federal Register notice announcing their completion published under this 0938-0786 control number on November 23, 2001 (66 FR 58741). The Federal Register notice served to comply with the Paperwork Reduction Act (PRA) and provided the public the opportunity to comment on the burden estimate or any other aspect of the protocols. The public comment period ended on January 22, 2002. The Office of Management and Budget required that the comments and responses on the protocols be included in the final EQR rule. We received comments from 13 organizations; these were reviewed and responses included in the preamble to the final rule.

The PRA approval of the protocols was renewed without change in 2006 and in 2009. At the time of the 2009 renewal, CMS was aware of the need to revise the protocols at a later time due to their use in the then newly-required Children's Health Insurance Program (CHIP) EQR reviews.

On July 1, 2010, CMS entered a contract with Provider Resources, Inc. (PRI) to revise the EQR Protocols for the first time since they were drafted in 2002. The revision was financed by CHIPRA funds and a principal reason for the revision was to add CHIP material to the protocols which had been designed for use in the Medicaid program. The revision also addressed numerous changes in law and quality practices beyond just the changes related to CHIPRA, including recommendations to voluntarily align with quality reporting opportunities under HITECH provisions of the American Recovery and Reinvestment Act of 2009, and the Affordable Care Act of 2010. The contract concluded at the end of 2010 and PRI delivered the revised protocols to CMS. The revised EQR Protocols received OMB approval in September 2012 for a three-year period, which expired September 30, 2015. On May 19, 2015, OMB renewed this PRA package without change; the current expiration date is May 31, 2018.

There are no proposed changes at this time to the EQR protocols. We anticipate revision of these protocols within the next three years to reflect changes related to CMS-2390-F (including the new mandatory EQR-related activity (network adequacy validation) and the new optional EQR-related activity (plan rating) and changes in quality review and measurement processes since 2012.

## A. Justification

1. Need and Legal Basis

Section 1932(c)(2)(A)(iii) requires that the Secretary have protocols developed to be used in EQRs.

Section 1932(c)(2)(A)(iv) requires that the results of EQR be made available to participating health care providers, enrollees and potential enrollees of the MCO.

2. Information Users

The law requires that the state agency provide to the EQRO information from the EQR-related activities, obtained through methods consistent with the Protocols specified by CMS (or with information from the Medicare or private accreditation review, in cases where the state uses the nonduplication provision). Information from EQR-related activities is generated by an EQRO, other state contractor that is not an MCO, PIHP, PAHP, or PCCM entity, or the state, and is used by the EQRO to determine the quality of care furnished by an MCO, PIHP, PAHP, or PCCM entity.

The regulation extends the availability of the results of EQR to the public. In addition to responding to requests, states must post the EQR technical reports on their websites. This allows Medicaid enrollees and potential enrollees to make informed choices regarding the selection of their providers. It also allows advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to Medicaid beneficiaries enrolled in Medicaid MCOs, PIHPs, PAHPs, and PCCM entities.

With respect to the nonduplication provision and the provision that allows for the exemption of EQR, these provisions do not relieve the state of its responsibility to ensure and monitor the access, timeliness, and quality of services are provided by the MCO, PIHP, or PAHP. Thus, information from the accreditation and Medicare review activities must be made available to the states agency in order for the state agency to use the information in its oversight of these organizations.

3. Use of Information Technology

The information is collected by the states. The decision as to whether or not collection methods can be improved with newer technology will be up to the states. Presently, states submit these reports to CMS by email. No signature, electronic or written, is required on the document.

4. Duplication of Efforts

These information collection requirements do not duplicate similar information collections. Rather, the intent is to provide states with an option to not have to duplicate Medicare or private accreditation review activities, thus enabling the state to minimize duplication of requirements placed on MCOs, PIHPs, and PAHPs with whom they contract.

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. Individuals and state governments are not included in the definition of a small entity.

As of 2012, 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 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 into §438.350 to the list of affected entities regarding the external quality review process. 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.

All cost estimates were derived from the Collection of Information section of the May 6, 2016 final rule (RIN 0938-AS25, CMS-2390-F). The estimated costs associated with the impacts on small entities listed above are primarily attributable to application of the external quality review requirements in §438.350 to PAHPs and PCCM entities. The application of the EQR requirements to both PAHPs and PCCM entities accounts for approximately $460,943 of the cumulative $4.5 million 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 May 6, 2016 final rule 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 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. Therefore, based on the estimates in the COI, we have determined that the May 6, 2016 final rule will not have a significant economic impact on a substantial number of small entities. In the proposed rule, we invited comment on our proposed analysis of the impact on small entities and on possible alternatives to provisions of the proposed rule that would reduce burden on small entities. We received no comments and are finalizing our analysis as proposed in this final rule.

6. Less Frequent Collection

As EQR by statute is an annual requirement, the information must be collected annually. If CMS were not to require states to collect this information annually, the states would be in violation of the law. Information from the state EQR technical reports is also used to inform the reports required by CHIPRA Section 401(c)(B) (Annual State Reports Regarding State-Specific Quality of Care Measures Applied Under Medicaid or CHIP) and by Affordable Care Act Section 2701 (Adult Health Quality Measures).

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 statue 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 die information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

Serving as the 60-day Federal Register notice, the NPRM published on June 1, 2015 (80 FR 31098; RIN 0938-AS25). PRA-related public comments were received. A summary of the comments and our response have been added to this package.

Additionally, while we did not develop a burden estimate for §438.350 in the proposed PRA package, upon further consideration, and in light of the application of EQR to PCCM entities described in §438.310(c)(2), we have determined it necessary to develop a burden for the amendment of EQRO contracts in states with MCOs and PIHPs which we assume will amend existing EQRO contracts to include PAHPs and PCCM entities.

Serving as the 30-day Federal Register notice, the final rule published on May 6, 2016 (81 FR 27498; RIN 0938-AS25). While the number of burden hours in the rule matches the figure in this information collection request, the number of respondents differ by 6 and the number of responses differ by 1,189. The discrepancy was caused by inadvertent double counting which did not become apparent until we assigned estimate ID numbers (Estimate 12.1 (S), Estimate 12.2 (S), etc.) to section 12 of this Supporting Statement to help OMB, the public, and all reviewers streamline their review of package. The ID numbers were not added to the rule.

9. Payment/Gift to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected as a result of these laws will be provided directly to states and will be subject to state-like freedom of information requirements. However, as per Section 1932(c)(2)(A)(iv) of the Act, the results of EQR may not be made available in a manner that discloses the identity of any individual patient.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates

*12.1 Wage Estimates*

To develop burden estimates, we used data from the U.S. Bureau of Labor Statistics' May 2014* 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 median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

**Note: The wage estimates are consistent with the hourly wages set out in the final rule. At the time of public inspection (April 25, 2016), the final rule's hourly wage estimates were in line with BLS' most up to date figures, namely May 2014.*

| Occupation Title | Occupation Code | Mean Hourly Wage ($/hr) | Fringe Benefit ($/hr) | Adjusted Hourly Wage ($/hr) |
|---|---|---|---|---|
| Business Operations Specialist | 13-1000 | 32.23 | 32.23 | 64.46 |
| Computer Programmer | 15-1131 | 39.16 | 39.16 | 78.32 |
| General and Operations Mgr | 11-1021 | 70.40 | 70.40 | 140.80 |
| Office and Administrative Support Worker | 43-9000 | 18.27 | 18.27 | 36.54 |

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.

*12.2 Information Collection Requirements*

The following information collection requirements and burden estimates replace those that were approved by OMB on May 19, 2015. See section 15 of this Supporting Statement for a discussion of the changes.

External Quality Review (§438.350)

This section describes the basic requirement for states contracting with MCOs, PIHPs, PAHPs, and select PCCM entities to conduct an annual external quality review for each contracted MCO, PIHP, PAHP, or PCCM entity described in §438.310(c)(2).

We estimate that there are 12 states that contract with PAHPs (of which 3 states contract with only PAHPs) and 10 states that contract with PCCM entities which will be required to undergo an annual EQR (of which 2 states contract only with PCCM entities). Therefore, we estimate that there are 17 states that contract with PAHPs or PCCM

entities in addition to MCOs and PIHPs which will amend their existing EQRO contracts. We estimate a one-time burden of 1 hr at $64.46/hr for a business operations specialist to amend the EQRO contract. In aggregate, we estimate a one-time state burden of 17 hr (17 states x 1 hr) and $1,095.82 (17 hr x $64.46/hr), annualized to **5.7 hr** and **$365.27** (**Estimate 12.1 (S)**). We are annualizing the one-time development burden since we do not anticipate any additional development burden after the 3-year approval period expires.

The estimated 3 states with only PAHPs and the estimated 2 states with only PCCM entities that do not currently have an EQRO contract would need to enter into a contract with an EQRO.

External Quality Review Protocols (§438.352)

There is no burden associated with this section, which describes the components of the EQR protocols, which are the instructions for the EQR-related activities described in §438.358. States, their contractors that are not MCOs, PIHPs, or PAHPs, or EQROs must conduct the EQR-related activities either using the EQR protocols or using methods consistent with these protocols. The burden associated with reading and following the EQR protocols to conduct the EQR-related activities is captured in the burden for §438.358.

Activities Related To External Quality Review (§438.358)

This section describes the mandatory and optional EQR-related activities, which may be performed by the state, its agent that is not an MCO, PIHP, PAHP, or PCCM entity described in §438.310(c)(2), or an EQRO. It also describes when EQROs may, at state's discretion, provide technical assistance to MCOs, PIHPs, and PAHPs to assist in the performance of mandatory and optional EQR-related activities.

Per §438.358(a)(1), the EQR-related activities described in paragraphs (b) and (c) may be conducted by the state, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)), or an EQRO; we describe the burden assuming that the state conducts these activities, though we believe the burdens will be similar regardless of who conducts each activity.

*Mandatory Activities*

The burden associated with the mandatory EQR-related activities described in §438.358(b)(1) is the time and effort for a state to conduct and document the findings of the four mandatory activities: (1) the annual validation of PIPs conducted by the MCO, PIHP, or PAHP, (2) the annual validation of performance measures calculated by the MCO, PIHP, or PAHP, (3) a review of MCO, PIHP, or PAHP compliance with structural and operational standards, performed once every 3 years; and (4) validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months. Each of the activities will be conducted on the 552 MCOs, PIHPs, and PAHPs that we estimate provide

Medicaid services.

The types of services provided by MCOs, PIHPs, and PAHPs, and the number of PIPs conducted and performance measures calculated will vary. Based on recent experience (for MCOs and PIHPs), we estimate that each MCO or PIHP will conduct 3 PIPs, each PAHP will conduct 1 PIP, and that each MCO, PIHP, or PAHP will calculate 3 performance measures. Furthermore, using the existing time estimates developed for MCOs and PIHPs for these activities, (and assuming that the same time estimates will also apply to PAHPs), we estimate it will take an average of 65 hr/PIP validation, 53 hr/performance measure validation, and 361 hr/compliance review (occurring once every 3 years) for a business operations specialist, at $64.46/hr, to conduct the mandatory EQR activities.

For MCOs and PIHPS, we estimate an aggregate annual state burden of **242,367.3 hr** (511 MCOs and PIHPs x [(65 hr x 3 PIP validations) + (53 hr x 3 performance measure validations) + (361 hr / 3 year compliance review)]) and **$15,622,996.16** (242,367.3 hr x $64.46/hr) for the first three mandatory EQR-related activities (**Estimate 12.2 (S)**).

For PAHPs, we estimate an aggregate annual state burden of **14,116.3 hr** (41 PAHPs x 344.3 hr [(65 hr x 1 PIP validations) + (53 hr x 3 performance measure validations) + (361 hr / 3 years compliance review)]) and **$909,936.70** (14,116.3 hr x $64.46/hr) for the first three mandatory EQR-related activities (**Estimate 12.3 (S)**).

The fourth mandatory EQR-related activity described in §438.358(b)(1)(iv) requires the validation of MCO, PIHP, and PAHP network adequacy during the preceding 12 months. States will conduct this activity for each MCO, PIHP, and PAHP. Given that this is a new activity, we do not have historic data on which to base an hourly burden estimate for the network validation process. We estimate that it will take less time than the validation of a PIP but more time than the validation of a performance measure. Therefore, we estimate an annual state burden of 60 hr at $64.46/hr for a business operations specialist to support the validation of network adequacy activity. In aggregate, we estimate a state burden of **33,120 hr** (552 MCOs, PIHPs, and PAHPs x 60 hr) and **$2,134,915.20** (33,120 hr x $64.46/hr) for the validation of network adequacy activity (**Estimate 12.4 (S)**).

Section 438.358(b)(2) describes the mandatory EQR-related activities which must be conducted for each PCCM entity (described in §438.310(c)(2)), specifically the activities described in §438.358(b)(1)(ii) and (iii). Given that we do not have data to estimate the time required for each of these activities for these PCCM entities, we rely on the time per activity estimates used for MCOs, PIHPs, and PAHPs; we assume the validation of one performance measure per PCCM entity (described in §438.310(c)(2)). Therefore, we estimate an aggregate annual state burden of **1,560 hr** (9 PCCM entities x 173.3 hr [(53 hr x 1 performance measure validations) + (361 hr / 3 years compliance review)]) and **$100,557.60** (1,560 hr x $64.46/hr) for the mandatory EQR-related activities for PCCM entities (described in §438.310(c)(2)) (**Estimate 12.5 (S)**).

The burden associated with §438.358(b)(1) also includes the time for an MCO, PIHP, or

PAHP to prepare the information necessary for the state to conduct the mandatory EQR-related activities. We estimate that it will take each MCO, PIHP, or PAHP 200 hr to prepare the documentation for these four activities, half (100 hr) at $64.46/hr by a business operations specialist and half (100 hr) at $36.54/hr by an office and administrative support worker.

The burden associated with §438.358(b)(2) also includes the time for a PCCM entity (described in §438.310(c)(2)) to prepare the information necessary for the state to conduct the mandatory EQR-related activities. Given the estimate of 200 hr for an MCO, PIHP, or PAHP, and that there are only 2 mandatory EQR-related activities for PCCM entities (described in §438.310(c)(2)), we estimate it will take 100 hr to prepare the documentation for these 2 activities, half (50 hr) at $64.46/hr by a business operations specialist and half (50 hr) at $36.54/hr by an office an administrative support worker.

In aggregate, we estimate an aggregate annual private sector burden of **111,300 hr** [(552 MCOs, PIHPs, and PAHPs x 200 hr) + (9 PCCM entities x 100 hr)] and **$5,620,650** [(55,950 hr x $64.46/hr) + (55,950 hr x $36.54/hr)] (**Estimate 12.6 (PS)**).

*Optional Activities*

Section 438.358(c) describes the six optional EQR-related activities: (1) validation of client level data (such as claims and encounters); (2) administration or validation of consumer or provider surveys; (3) calculation of performance measures; (4) conduct of PIPs; (5) conduct of focused studies; and (6) assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with §438.334. As with the mandatory activities described in §438.358(b), these activities may be conducted by the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO, but for the purposes of this burden estimate we assume that the state conducts the activities.

We have no data to estimate the hours associated with how long it will take to conduct the optional EQR activities. Without that information, our best guess is that it will take 350 hr to validate client level data and 50 hr to validate consumer or provider surveys. We estimate it will take three times as long to calculate performance measures (159 hr) as it takes on average to validate and three times as long to conduct PIPs and focused studies (195) as it takes on average to validate PIPs. We also estimate that it will take three times as long to administer a consumer or provider survey than it takes to validate a survey (150 hr).

Based on our review of recent EQR technical report submissions we estimate and assume that each year 10 percent (51) of MCOs and PIHPs will be subject to each of the optional EQR-related activities, though we note that the exact states and number vary from year to year. Regarding the administration or validation of consumer or provider surveys, we assume that half of the MCOs and PIHPs (25) will administer surveys while half (26) will validate surveys. We also estimate that a mix of professionals will work on each optional EQR-related activity: 20 percent by a general and operations manager ($140.80/hr); 25 percent by a computer programmer ($78.32/hr); and 55 percent by a business operations

specialist ($64.46/hr). For the purposes of this estimate, we assume that the 10 percent of affected MCOs and PIHPs operate within 10 percent of states that contract with MCOs and PIHPs (4 states). We understand that this estimate may not reflect the number of states that require these optional EQR-related activities, and that there is variation in the number of plans that operate within a given state.

- To validate client level data, we estimate 17,850 hr (51 MCOs and PIHPs x 350 hr) and $1,484,995.05 [(17,850 hr x 20 percent x $140.80/hr) + (17,850 hr x 25 percent x $78.32/hr) + (17,850 hr x 55 percent x $64.46/hr)].

- To administer consumer or provider surveys, we estimate 3,750 hr (25 MCOs and PIHPs x 150 hr) and $311,973.75 [(3,750 hr x 20 percent x $140.80/hr) + (3,750 hr x 25 percent x $78.32/hr) + (3,750 hr x 55 percent x $64.46/hr)].

- To validate consumer or provider surveys, we estimate 1,300 hr (26 MCOs and PIHPs x 50 hr) and $108,150.90 [(1,300 hr x 20 percent x $140.80/hr) + (1,300 hr x 25 percent x $78.32/hr) + (1,300 hr x 55 percent x $64.46/hr)].

- To calculate performance measures, we estimate 8,109 hr (51 MCOs and PIHPs x 159 hr) and $674,612.04 [(8,109 hr x 20 percent x $140.80/hr) + (8,109 hr x 25 percent x $78.32/hr) + (8,109 hr x 55 percent x $64.46/hr)].

- To conduct PIPs, we estimate 9,945 hr (51 MCOs and PIHPs x 195 hr) and $827,354.39 [(9,945 hr x 20 percent x $140.80/hr) + (9,945 hr x 25 percent x $78.32/hr) + (9,945 hr x 55 percent x $64.46/hr)].

- To conduct focused studies, we estimate 9,945 hr (51 MCOs and PIHPs x 195 hr) and $827.354.39 [(9,945 hr x 20 percent x $140.80/hr) + (9,945 hr x 25 percent x $78.32/hr) + (9,945 hr x 55 percent x $64.46/hr)].

In aggregate, the annual state burden for optional EQR-related activities for MCOs and PIHPs is **50,899 hr** (17,850 hr + 3,750 hr + 1,300 hr + 8,109 hr + 9,945 hr + 9,945 hr) and **$4,234,440.51** [(50,899 hr x 20 percent x $140.80/hr) + (50,899 hr x 25 percent x $78.32/hr) + (50,899 hr x 55 percent x $64.46/hr)] (**Estimate 12.7 (S)**).

The optional EQR-related activities described in §438.358(c) may also be conducted on PAHPs and PCCM entities (described in §438.310(c)(2)). Since neither PAHPs or PCCM entities (described in §438.310(c)(2)) have historically been subject to EQR, we do not have any data on which to base an estimate regarding how states will apply the optional EQR-related activities to these delivery systems. Therefore, we will apply the time, wage, and participation estimates developed for MCOs and PIHPs to PAHPs and PCCM entities (described in §438.310(c)(2)).

- To validate client level data, we estimate 2,100 hr (6 PAHPs and PCCM entities x 350 hr) and $174,705.30 [(2,100 hr x 20 percent x $140.80/hr) + (2,100 hr x 25 percent x $78.32/hr) + (2,100 hr x 55 percent x $64.46/hr)].

- To administer consumer or provider surveys, we estimate 450 hr (3 PAHPs and PCCM entities x 150 hr) and $21,981 [(450 hr x 20 percent x $140.80/hr) + (450 hr x 25 percent x $78.32/hr) + (450 hr x 55 percent x $64.46/hr)].

- To validate consumer or provider surveys, we estimate 150 hr (3 PAHPs and PCCM entities x 50 hr) and $12,478.95 [(150 hr x 20 percent x $140.80/hr) + (150 hr x 25 percent x $78.32/hr) + (150 hr x 55 percent x $64.46/hr)].

- To calculate performance measures, we estimate 954 hr (6 PAHPs and PCCM entities x 159 hr) and $79,366.12 [(954 hr x 20 percent x $140.80/hr) + (954 hr x 25 percent x $78.32/hr) + (954 hr x 55 percent x $64.46/hr)].

- To conduct PIPs, we estimate 1,170 hr (6 PAHPs and PCCM entities x 195 hr) and $97,335.81 [(1,170 hr x 20 percent x $140.80/hr) + (1,170 hr x 25 percent x $78.32/hr) + (1,170 hr x 55 percent x $64.46/hr)].

- To conduct focused studies, we estimate 1,170 hr (6 PAHPs and PCCM entities x 195 hr) and $97,335.81 [(1,170 hr x 20 percent x $140.80/hr) + (1,170 hr x 25 percent x $78.32/hr) + (1,170 hr x 55 percent x $64.46/hr)].

In aggregate, the total annual state burden for optional EQR-related activities for PAHPs and PCCM entities (described in §438.310(c)(2)) is **5,994 hr** (2,100 hr + 450 hr + 150 hr + 954 hr + 1,170 hr + 1,170 hr) and **$498,658.84** [(5,994 hr x 20 percent x $140.80/hr) + (5,994 hr x 25 percent x $78.32/hr) + (5,994 hr x 55 percent x $64.46/hr)] (**Estimate 12.8 (S)**).

Section 438.358(c)(6) allows a state to contract with an EQRO to support the quality rating of MCOs, PIHPs, and PAHPs consistent with §438.334. We do not believe that the effort required to rate a plan changes based on which entity (state or EQRO) develops the plan rating. Therefore, we believe that any burden associated with this optional EQR-related activity will only offset the burden associated with §438.334(d).

Nonduplication of Mandatory Activities (§438.360)

This section describes the circumstances under which the state may use information about an MCO, PIHP, or PAHP obtained from a Medicare or private accreditation review in place of information otherwise generated about the plan through the EQR-related activities described in § 438.358.

Section 438.360(a) grants states the option to use the information obtained from a Medicare or private accreditation review of an MCO, PIHP, or PAHP in place of information otherwise generated from the three mandatory activities specified in §438.358(b)(1)(i) through (iii). Specifically, this section allows states to apply the non-duplication option to all MCOs, PIHPs, and PAHPs and it allows states to apply the non-duplication option to the validation of performance measures, the validation of PIPs, and

to the compliance review. Section 438.360(c) requires states to address the use of non-duplication as an element of the quality strategy.

*External Quality Review Report*

Section 438.360(b) describes when a state may elect to use information from a Medicaid or private accreditation review in place of information that would otherwise be generated by the mandatory EQR-related activities in §438.358(b)(1)(i) through (iii). The burden associated with non-duplication is the time and effort for an MCO, PIHP, or PAHP to disclose the reports, findings, and other results of the Medicare or private accreditation review to the state agency.

While states could elect to allow all 552 MCOs, PIHPs, and PAHPs to substitute information from a Medicare or private accreditation review for the three mandatory EQR-related activities specified at §438.358(b)(1)(i) through (iii), in practice we find that states utilize this option infrequently. Therefore, we estimate that states will apply the non-duplication option to 10 percent (55) of MCOs (33), PIHPs (18), and PAHPs (4). We estimate an annual private sector burden of 2 hr at $64.46/hr for a business operations specialist and 6 hr at $36.54/hr for an office and administrative support worker to disclose the necessary documentation to the state each year for a single MCO or PIHP.

In aggregate, we estimate a private sector burden of **408 hr** (51 MCOs and PIHPs x 8 hr) and **$17,756.16** [(51 MCOs and PIHPs x (2 hr x $64.46/hr) + (6 hr x $36.54/hr)] (**Estimate 12.9 (PS)**).

Under this rule, states may apply the nonduplication provisions to PAHPs. In aggregate, we estimate **32 hr** (4 PAHPs x 8 hr) and **$1,392.64** [4 PAHPs x (2 hr x $64.46/hr) + (6 hr x $36.54/hr)] (**Estimate 12.10 (PS)**).

The process in §438.360(b) includes the provision of all of the reports, findings, and other results of the Medicare or private accreditation review to the appropriate EQRO by the state agency. We estimate it will take, on average, 2 hr at $36.54/hr for an office and administrative support worker to disclose the necessary documentation to the appropriate EQRO.

In aggregate, we estimate an annual state burden of **110 hr** (55 MCOs, PIHPs, and PAHPs x 2 hr) and **$4,019.40** (110 hr x $36.54/hr) to forward non-duplication-related documentation to the EQROs (**Estimate 12.11 (S))**.

Assuming that states will apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we estimate that this provision will offset the burden associated with §438.358(b)(1)(i) through (iii) for 51 MCOs and PIHPs, and 4 PAHPs (since these activities will no longer be necessary for these 55 plans). Consistent with the estimates used in §438.358(b)(1)(i) through (iii), we estimate an aggregated offset of annual state burden of **–25,566.50** hr [(-51 MCOs and PIHPs x 474.3 hr) + (-4 PAHPs x 344.3 hr)] and **-$1,648,016.59** (-25,566.50 hr x $64.46) (**Estimate 12.12 (S))**.

Additionally, the MCOs, PIHPs, and PAHPs subject to non-duplication will not have to prepare the documentation necessary for the three mandatory EQR-related activities. Based on the assumption in §438.358(b)(1) that an MCO, PIHP, or PAHP will need 200 hr to prepare the documentation for the four mandatory activities, we estimate that it will take 150 hr to prepare the documentation for the three activities subject to non-duplication, half (100 hr) at $64.46/hr by a business operations specialist and half (100 hr) at $36.54/hr by an office and administrative support worker.

In aggregate, we estimate a decrease in annual private sector burden of **-8,250 hr** (-55 MCOs, PIHPs, and PAHPs x 150 hr) and **-$416,625** [(-4,125 hr x $64.46/hr) + (-4,125 x $36.54)] **(Estimate 12.13 (PS)).**

Exemption from External Quality Review (§438.362)

This section describes the circumstances under which a state may exempt an MCO from EQR.

Under §438.362, exempted MCOs have to provide (annually) to the state agency the most recent Medicare review findings reported to the MCO by CMS or its agent. Of the approximately 335 MCOs, we estimate that approximately half (168) might provide Medicare services in addition to Medicaid services. Of these 168 MCOs that might potentially provide Medicare services in addition to Medicaid services, we further estimate that state agencies will allow approximately 10 percent (17) of the MCOs to be exempt from the EQR process.

We estimate an annual private sector burden of 8 hr (2 hr at $64.46/hr for a business operations specialist and 6 hr at $36.54/hr for an office and administrative support worker) for an MCO to prepare and submit the necessary documentation to the state agency. In aggregate, we estimate **136 hr** (17 MCOs x 8 hr) and **$5,918.72** (17 MCOs x [(2 hr x $64.46/hr) + (6 hr x $36.54/hr)]) (**Estimate 12.14 (PS)**).

External Quality Review Results (§438.364)

This section describes the minimum information that must be included in a state's annual EQR technical report which summarizes findings on access and quality of care. It also describes how the state must make this information available to the public, which includes a requirement that this action may not disclose the identity of any patient.

*Information That Must be Produced*

Section 438.364(a) describes the information that will be included in the annual detailed technical report that is the product of the EQR. Section 438.364(a)(1)(iii) specifies that the EQR technical report includes baseline and outcomes data regarding PIPs and performance measures. Many states already provide much of this information in their final EQR technical report. The burden of compiling this data for MCOs, PIHPs, PAHPs,

and select PCCM entities is captured in §438.358.

Under §438.364(a)(3), EQR technical reports will include recommendations on how the state can use the goals and objectives of its managed care quality strategy to support improvement in the quality, timeliness, and access to care for beneficiaries. We believe that states will amend their EQRO contracts to address the changes to §438.364(a). We estimate a one-time state burden of 0.5 hr at $64.46/hr for a business operations specialist to amend the EQRO contract in the estimated 37 states with existing EQRO contracts. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate, we estimate a state burden of 18.5 hr (37 states x 0.5 hr) and $1,192.51 (18.5 hr x $64.46/hr), annualized to **6.2 hr** and **$397.50** (**Estimate 12.15 (S)**). We believe that the 5 states that contract only with PAHPs and PCCM entities will incorporate this section into their initial EQRO contracts, and therefore we do not believe there is an EQRO amendment burden associated with the changes to this section for those 5 states.

*Revision*

Section 438.364(b)(1) clarifies that the EQRO will produce and submit to the state an annual EQR technical report, and that states may not substantively revise the report without evidence of error or omission. This is consistent with existing policy and should not pose a burden on the states or the private sector. The April 30th deadline for the finalization and submission of EQR technical reports is consistent with existing subregulatory guidance.

While we do not anticipate that this change would pose a significant burden on states or the private sector, we estimate that this provision may necessitate a change in a state's EQRO contract for approximately 10 states. In this regard, we estimate a one-time state burden of 0.5 hr at $64.46/hr for a business operations specialist to modify the EQRO contract. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 5 hr (10 states x 0.5 hr) and $322.30 (5 hr x $64.46/hr), annualized to **1.7 hr** and **$107.43** (**Estimate 12.16 (S)**).

*Availability of Information*

Under §438.364(c)(ii), each state agency will provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. States will also make the most recent EQR technical report publicly available on the state's website, the burden for which is included in §438.10.

We believe that by making these reports available online, states will be able to

significantly decrease the burden associated with responding to requests from the public for this information, as it will already be easily accessible. The burden associated with section is the time and effort for a state agency to furnish copies of a given technical report to interested parties. In light of recent technological advances, we estimate an annual state burden of 5 minutes (on average) at $36.54/hr for an office and administrative support worker to disclose the reports (per request), and that a state will receive five requests per MCO, PIHP, PAHP or PCCM entity (described in §438.310(c)(2).

In aggregate, we estimate **233.7 hr** [(561 MCOs, PIHPs, PAHPs, and PCCM entities x 5 requests x 5 min) / 60 min] and **$8,539.40** (233.7 hr x $36.54/hr). (**Estimate 12.17 (S)**).

Federal Financial Participation (FFP) (§438.370)

This section describes the availability of FFP for EQR and EQR-related activities.

Section 438.370(c) requires states to submit EQRO contracts to CMS for review and approval prior to claiming FFP at the 75 percent rate. Since most states already consult with CMS regarding EQRO contracts, we estimate only 12 states will need to amend their policies and procedures to comply with this process. We estimate a one-time state burden of 0.5 hr at $64.46/hr for a business operations specialist to amend their state's policies and procedures.

In aggregate, we estimate 6 hr (12 states x 0.5 hr) and $386.76 (6 hr x $64.46/hr), annualized to **2.0 hr** and **$128.92** (**Estimate 12.18 (S)**). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

The 12 states which do not currently work with CMS on their EQRO contracts will need to submit the EQRO contracts to CMS for review and approval if they plan to claim the enhanced 75 percent federal match. We estimate a one-time state burden of 0.25 hr at $36.54/hr for an office and administrative support worker to submit the EQRO contract to CMS.

In aggregate, we estimate 3 hr (12 states x 0.25 hr) and $109.62 (3 hr x $36.54/hr), annualized to **1.0** hr and **$36.54** (**Estimate 12.19 (S)**). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

*12.3 Summary of Burden Estimates*

**Summary of Annual Burden Estimates: States (S)**

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

| Estimate No. | 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 (S) | 438.350 | 17 | 17 | 1 | 17.00 | 64.46 | 64.46 | 1,095.82 | once | R | 5.70 | 365.27 |
| 12.2 (S) | 438.358(b)(1)(i)-(iii) | 37 | 511 | 474.3 | 242,367.30 | 64.46 | 30,573.38 | 15,622,996.16 | annual | R | 242,367.30 | 15,622,996.16 |
| 12.3 (S) | 438.358(b)(1)(i)- (iii) | 12 | 41 | 344.3 | 14,116.30 | 64.46 | 22,193.58 | 909,936.70 | annual | R | 14,116.30 | 909,936.70 |
| 12.4 (S) | 438.358(b)(1)(iv) | 37 | 511 | 60 | 33,120.00 | 64.46 | 3,867.60 | 2,134,915.20 | annual | R | 33,120.00 | 2,134,915.20 |
| 12.5 (S) | 438.358(b)(2) | 5 | 9 | 173.3 | 1,560.00 | 64.46 | 11,170.92 | 100,577.60 | annual | R | 1,560.00 | 100,577.60 |
| 12.7 (S) | 438.358(c)(1) | 51 | 255 | 199.6 | 50,899.00 | varies | 16,605.65 | 4,234,440.51 | annual | R | 50,899.00 | 4,234,440.51 |
| 12.8 (S) | 438.358(c)(1) | 51 | 30 | 199.8 | 5,994.00 | varies | 16,621.97 | 498,658.84 | annual | R | 5,994.00 | 498,658.84 |
| 12.12 (S) | 438.360(b) | 40 | -51 | 474.3 | -24,189.30 | 64.46 | 30,573.38 | -1,559,242.28 | annual | R | -24,189.30 | -1,559,242.28 |
| 12.12 (S) | 438.360(b) | 40 | -4 | 344.3 | -1,377.20 | 64.46 | 22,193.58 | -88,774.31 | annual | R | -1,377.20 | -88,774.31 |
| 12.15 (S) | 438.364(a) | 37 | 37 | 0.5 | 18.50 | 64.46 | 32.23 | 1,192.51 | once | R | 6.20 | 397.50 |
| 12.16 (S) | 438.364(b)(1) | 10 | 10 | 0.5 | 5.00 | 64.46 | 32.23 | 322.30 | once | R | 1.70 | 107.43 |
| 12.18 (S) | 438.370(c) | 12 | 12 | 0.5 | 6.00 | 64.46 | 32.23 | 386.76 | once | R | 2.00 | 128.92 |
| 12.19 (S) | 438.370(c) | 12 | 12 | 0.25 | 3.00 | 36.54 | 9.14 | 109.62 | once | R | 1.00 | 36.54 |
| | *SUBTOTAL: Reporting* | *51* | *1,390* | *Varies* | *322,539.60* | *Varies* | *15,724.18* | *21,856,615.43* | *n/a* | *R* | *322,506.70* | *21,854,544.08* |
| 12.11 (S) | 438.360(b) | 40 | 55 | 2 | 110.00 | 36.54 | 73.08 | 4,019.40 | annual | TPD | 110.00 | 4,019.00 |
| 12.17 (S) | 438.364(c)(2) | 42 | 2,805 | 0.0833 | 233.70 | 36.54 | 3.01 | 8,539.40 | annual | TPD | 233.70 | 8,539.40 |
| | *SUBTOTAL: Third-Party Disclosure* | *42* | *2,860* | *varies* | *343.70* | *36.54* | *76.09* | *12,558.80* | annual | TPD | *343.70* | *12,558.40* |
| **TOTAL** | | **51** | **4,250** | **varies** | **322,883.30** | **varies** | **15,800.27** | **21,869,174.23** | **n/a** | **n/a** | **322,850.10** | **21,867,102.48** |

*Please see text under this section for detailed wage figures.

## Summary of Annual Burden Estimates: Private Sector (PS)

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

| Estimate No. | CFR section | # Respondents | # responses | Burden per response (hours) | Total Annual Hours | Labor Rate ($/hr) * | Cost ($) per Response | Total cost ($) | Frequency | Response Type | Annualized hours* | Annualized Costs ($) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 12.6 (PS) | 438.358(b)(1) | 561 | 561 | 200 | 111,300 | varies | 10,018.98 | 5,620,650.00 | annual | R | 111,300 | 5,620,650.00 |
| 12.9 (PS) | 438.360(a) | 51 | 51 | 8 | 408 | varies | 348.16 | 17,756.16 | annual | R | 408 | 17,756.16 |
| 12.10 (PS) | 438.360(a) | 4 | 4 | 8 | 32 | varies | 348.25 | 1,392.64 | annual | R | 32 | 1,392.64 |
| 12.13 (PS) | 438.360(a)(3) | -55 | -55 | 150 | -8,250 | varies | 4,834.50 | -416625.00 | annual | R | -8,250 | -416,625.00 |
| | *SUBTOTAL: Reporting* | *561* | *561* | *Varies* | *103,490* | *Varies* | *9,310.47* | *5,223,173.8* | *n/a* | *R* | *103,490* | *5,223,173.8* |
| 12.14 (PS) | 438.362 | 17 | 17 | 8 | 136 | varies | 348.16 | 5,918.72 | annual | TPD | 136 | 5,918.72 |
| | *SUBTOTAL: Third-Party Disclosure* | *17* | *17* | *8* | *136* | *varies* | *348.16* | *5,918.72* | *n/a* | *TPD* | *136* | *5,918.72* |
| **TOTAL** | | **561** | **578** | **varies** | **103,626** | **varies** | **9,658.63** | **5,229,092.52** | **n/a** | **n/a** | **103,626** | **5,229,092.52** |

*Please see text under this section for detailed wage figures.

## Summary of Annual Burden Estimates: State Governments and Private Sector

| Estimate No. | # Respondents | # responses | Burden per response (hours) | Total Annual Hours | Labor Rate ($/hr) * | Cost ($) per Response | Total cost ($) | Frequency | Response Type | Annualized hours* | Annualized Costs ($) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| State Governments (S) | 51 | 4,250 | Varies | 322,883 | varies | 15,800 | 21,869,174 | Varies | n/a | 322,850 | 21,867,103 |
| Private Sector (PS) | 561 | 578 | Varies | 103,626 | varies | 9,659 | 5,229,093 | Varies | n/a | 103,626 | 5,229,093 |
| **TOTAL** | **612** | **4,828** | **Varies** | **426,509** | **varies** | **25,459** | **27,098,267** | **Varies** | **n/a** | **426,476** | **27,096,195** |

13. Capital Costs

There are no capital or maintenance costs.

14. Cost to Federal Government

This collection involves both private sector (MCOs, PIHPs, PAHPs, and PCCM entities) and public sector (state government).

Total annualized private sector costs are $5,229,092.52. Consistent with the assumptions used for the private sector match rate in the final rule (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 $3,055,881.66.

There are two Federal match rates for EQR: 75 percent for EQR and EQR-related activities conducted by EQROs on MCOs, and 50 percent for EQR and EQR-related activities conducted on PIHPs, PAHPs, and PCCM entities by any entity, or on MCOs by non-EQROs.

Of the total annualized public sector costs ($21,867,102.58), we estimate that $12,901,590.18 will be eligible for the 75 percent Federal match rate and $8,965,511.82 will be eligible for the 50 percent Federal match rate. Therefore, the Federal share for annualized public sector costs is $14,158,948.55.

Total annualized Federal share (private and public sector) is **$17,214,830.21**.

15. Program or Burden Changes

Outside of adding a placeholder for the expiration date on the EQR Protocols Introduction, there are no other changes to the protocol documents.

The currently approved information collection request sets out only one ICR. This 2016 iteration corrects the currently approved information collection request by setting out two ICRS: one for states and another for the private sector.

Adjustments have been made to account for: (1) changes to the regulations per CMS-2390-F (see table set out below), (2) mathematical errors and estimate revisions in regards to the number of respondents, the type of respondents, annual responses, and annual hour burden, and (3) updated BLS job titles and wages.

The CMS-2390-F final rule removed the CHIP EQR burden from this information collection request and moved it under a separate PRA package (CMS-10554, OMB 0938-1282) which contains all of the CHIP managed care burden, including EQR.

Several sections, including 438.360, 438.362 and 438.364, had previously approved burdens in the 2009 package that were inadvertently excluded from the 2012 renewal package. This error was carried into the 2015 renewal without change package. We identified this error in the Collection of Information discussion in the May 6, 2016 final rule (RIN 0938-AS25, CMS-2390-F) and have accounted for the changes in burden below.

Sections 438.350 and 438.370 did not have previously approved burden estimates. In light of the application of EQR to PAHPs and certain PCCM entities, we have determined it necessary to develop a burden for states to amend their EQRO contracts to include PAHPs and PCCM entities, if applicable.

438.352: The previously approved burden under control number 0938-0786 (CMS-R-305) for the three mandatory EQR-related activities assumed that each of the then-estimated 458 MCOs and PIHPs validate one PIP by a professional at $63/hr for 65 hr, validate one performance measure by a professional at $63/hr for 53 hr, and complete an annual a compliance review by a professional at $63/hr for 361 hr. The previously approved annual burden was 219,382 hr (479 hr x 458 MCOs and PIHPs) and $13,821,066 (219,382 hr x $63/hr). The burden also included an estimated 160 hr per MCO or PIHP to prepare the information for the three existing mandatory EQR-related activities (finalized as §438.358(b)(1)(i) through (iii)), half by a professional at $63/hr and half by clerical staff at $12/hr. The previously approved burden for information preparation was 73,280 hr (438 MCOs and PIHPs x 160 hr) and $2,748,000 [(36,640 hr x $63/hr) + (36,640 hr x $12/hr)]. We believe that the burden associated with the completion of the EQR-related activities is better captured in §438.358; therefore we are removing the burden previously associated with §438.352 and instead capturing its associated burden under §438.358. Therefore, there is no burden associated with §438.352.

Section 438.358 did not have previously approved burden estimates. Instead, the information collections now associated with this section were previously associated with §438.352. In addition to moving and replacing the collections previously associated with §438.352 to this section, this section includes new burden from the May 6, 2016 final rule (RIN 0938-AS25, CMS-2390-F): specifically: (1) the burden for the EQR-related activities for PAHPs and PCCM entities (described at §438.310(c)(2)); the new mandatory EQR-related activity in §438.358(b)(1)(iv), network adequacy validation; and the new optional EQR-related activity in §438.358(c)(6), assistance with the quality rating of MCOs, PIHPs, and PAHPs.

438.360: The previously approved burden under control number 0938-0786 (CMS-R-305, 2009 package) estimated that 336 MCOs and/or PIHPs take advantage of the nonduplication provision, requiring 8 hr at $37.50/hr per MCO or PIHP to disclose the necessary information to the state, for a total previously approved burden of 2,688 hr (336 MCOs and PIHPs x 8 hr) and $100,800 (2,688 hr x $37.50/hr). Under the final rule, we described our belief that use of electronic tracking and transmission tools has significantly decreased the hourly burden associated with state staff forwarding the

documentation to the EQRO. Given the changes in estimation related to the final rule (see section 12.2 above), we estimate a change in burden of -2,578 hr (110 hr – 2,688 hr) and -$96,780.60 ($4,019.40 - $100,800).

438.362: Section 438.362 of the May 6, 2016 reflects that PIHPs cannot be exempted from EQR, as they do not qualify as a MA Organization under part C of Title XVII of the Act or under section 1876 of the Act, and they do not qualify as an MCO under section 1903(m) of the Act.

The previously approved burden under control number 0938-0786 (CMS-R-305, 2009 package) estimated that states would allow 10 percent (20) of the 202 MCOs (which might provide Medicare services in addition to Medicaid services) to be exempt from the EQR process, and that it would take each MCO approximately 8 hr at $37.50/hr to prepare the necessary materials for a total burden of 160 hr (20 MCOs x 8 hr) and $6,000 (160 hr x $37.50/hr). Given the changes in estimation related to the final rule (see section 12.2 above), we estimate a change in burden of -24 hr (136 hr –160 hr) and -$81.28 ($5,918.72 - $6,000).

438.364: The previously approved burden under control number 0938-0786 (CMS-R-305) estimates a burden of 91,600 hr and $1,099,200. This assumed 329 MCOs and 129 PIHPs (for a total of 458), 25 requests per MCO or PIHP, and 8 hr to respond to each request by staff at $12/hr. In light of recent technological changes described in this section of this final rule, we now estimate an annual state burden of 5 min (on average) at $36.54/hr for an office and administrative support worker to disclose the reports (per request), and that a state will receive five requests per MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)) per year. Overall, we estimate a change in burden of -91,366.3 hr (233.7 hr - 91,600 hr) and -$1,090,660.6 ($8,539.40 - $1,099,200).

The following table summarizes, at the section level, the annualized changes to hour and cost burdens as compared to the most recent available supporting statement estimates.

| CFR Section | Hours | | | Costs | | | Reason for Change |
|---|---|---|---|---|---|---|---|
| | Previous | Revised | Difference | Previous | Revised | Difference | |
| **438.350 EQR** | --- | 5.7 | 5.7 | --- | $365.27 | $365.27 | • Regulatory change (expansion of EQR to PAHPs)<br>• Estimate Change: Changes to EQR contracts |
| **438.352 EQR Protocols** | 451,288 | 0 | -451,288 | $33,032,025 | $0 | ($33,032,025) | • Estimate change: burden is more accurately captured under 438.358.<br>• PRA change: removal of |

| CFR Section | Hours | | | Costs | | | Reason for Change |
|---|---|---|---|---|---|---|---|
| | Previous | Revised | Difference | Previous | Revised | Difference | |
| | | | | | | | CHIP EQR burden from this package and into CMS-10554. |
| **438.358 EQR-related activities** | --- | 459,356.60 | 459,356.60 | --- | $29,122,175.01 | $29,122,175.01 | • Regulatory change: addition of mandatory and voluntary EQR-related activities, expansion of EQR to PAHPs.<br>• Estimate change: movement of burden from 438.352 to 438.358, number of entities. |
| **438.360 EQR Nonduplication** | --- | -33,266.50 | -33,266.50 | --- | ($2,041,473.95) | ($2,041,473.95) | • Regulatory change (expansion of EQR to PAHPs).<br>• Estimate change: developed estimate to offset EQR-related activity costs that would otherwise occur without nonduplication. |
| **438.362 EQR Exemption** | --- | 136 | 136 | --- | $5,918.72 | $5,918.72 | • Regulatory change: expansion of EQR to PAHPs. |
| **438.364 EQR Results** | --- | 241.6 | 241.6 | --- | $9,044.33 | $9,044.33 | • Regulatory change: expansion of EQR to PAHPs, posting of EQR technical reports on states' websites.<br>• Estimate change: time required to |

| CFR Section | Hours | | | Costs | | | Reason for Change |
|---|---|---|---|---|---|---|---|
| | Previous | Revised | Difference | Previous | Revised | Difference | |
| | | | | | | | respond to requests for EQR technical reports. |
| **438.370 FFP** | --- | 3 | 3 | --- | $165.46 | $165.46 | • Regulatory change: requiring submission of EQRO contracts to CMS for review in order to claim 75 percent match rate. |
| **TOTAL** | 451,288 | 426,476 | -24,812 | $33,032,025 | $27,096,194.84 | $(5,935,830.16) | |

16. Publication and Tabulation Dates

The EQR must, at a minimum, result in a detailed technical report that summarizes the findings on access and quality of care. This must include:

1) A description of the manner in which the data from the EQR-related activities were aggregated and analyzed, and the conclusions drawn by the EQRO regarding the quality, timeliness, and access to care provided by the MCO, PIHP, PAHP or PCCM entity;

2) Details for each EQR-related activity, including the objectives, technical methods of data collection and analysis, description of the data obtained (including validated performance measurement data for each activity conducted), and conclusions drawn from the data;

3) An assessment of the strength and weaknesses of each MCO, PIHP, PAHP, or PCCM entity with respect to timeliness, access, and quality of the health care services furnished to Medicaid beneficiaries;

4) Recommendations for improving the quality of the services furnished by each MCO, PIHP, PAHP, and PCCM entity, including how the state can target goals and objectives in its quality strategy (required under §438.340) to support improvement in the quality, timeliness, and access to services;

5) Methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities consistent with guidance included in the EQR protocols issued in accordance with §438.352; and

6) An assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR .

The annual EQR technical report will be submitted by the contracting EQRO to the state, which will then submit it to CMS, post it on the state's website, and provide this information upon request.

CMS will use the state-provided EQR technical reports in the development of the reports required by CHIPRA Section 401(c)(B) (Annual State Reports Regarding State-Specific Quality of Care Measures Applied Under Medicaid or CHIP) and by Affordable Care Act Section 2701 (Adult Health Quality Measures)..

CMS intends to maintain a list of hyperlinks on Medicaid.gov to states' websites where EQR technical reports are posted in order to improve public transparency.

17. Expiration Date

This package effectuates statutory and regulatory requirements that do not include an expiration date; therefore, we intend to maintain its approval indefinitely. It also includes the EQR protocols; we will revise this package whenever the EQR protocols are revised.

We will display OMB's expiration date.

18. Certification Statement

There are no exceptions to the certification statement.