

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

CMS published a rule concerning external quality review (EQR) of Medicaid managed care organizations (MCOs) 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 a managed care organization (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 federal financial participation for these activities. The January 24, 2003 final rule also 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 EQR 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). CMS updated the information collection (but not the included protocols) to align with the EQR provisions of the final rule; this update was approved by OMB on June 16, 2017 with an expiration date of June 20, 2020 (ICR Reference Number 201611-0938-016).

This 2019 information collection request revises the eight existing EQR protocols, which are currently approved by OMB and were last revised in 2012. The revisions include: 1) consolidate the existing EQR protocols and associated worksheets and appendices into one document; 2) restructure and revise the documents to simplify the narrative flow and usability; 3) update the protocols to include current best practices; and 4) align the existing protocols, appendices, and worksheets with the 2016 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 (nonduplication). Further, and consistent with BBA provisions, states may exempt certain MCOs from the annual EQR process.

EQR Technical Reports

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 to 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 (including PIHPs, PAHPs, and PCCM entities), are eligible for a 50 percent match rate.

EQR-Related Activities

States that contract with MCOs, PIHPs, PAHPs, and certain PCCM entities to deliver Medicaid services must ensure that a qualified EQRO conducts an EQR of each plan each year. The EQR-related activities provide the information used by an EQRO for the EQR. 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 the 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 managed care plans (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.

The intention of this revision is to align the existing protocols with the May 2016 final rule (RIN 0938-AS25, CMS-2390-F), to update the procedures to reflect modern technology and quality approaches, and to modernize the format of the documents. As a part of this modernization, the multiple documents which made up the 2012 version of the protocols were condensed into a single revised file with intra-document hyperlink capabilities and streamlined narrative flow to improve usability. As required by statute (section 1932(c)(2)(A)(iii)), CMS consulted with the National Governors' Association (NGA) during the development of the revised protocols.

CMS anticipates revision of this information collection within the next three years to reflect the remaining changes related to CMS-2390-F, those being the new mandatory EQR-related activity (network adequacy validation) and the new optional EQR-related activity (plan rating).

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). The EQR-related activities may be conducted by an EQRO, a state contractor that is not an MCO, PIHP, PAHP, or PCCM entity, or the state; the information generated by the EQR-related activities 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 annual EQR technical reports on their websites by April 30th. 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 state 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 were 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 was 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.

Estimated costs derived from the Collection of Information section of the May 6, 2016 final rule (RIN 0938-AS25, CMS-2390-F) and 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 (as calculated in the May 2016 final rule) accounted 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 estimated 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 was less than \$0.1 million, or less than 1 percent of the \$38.5 million threshold. The total estimated annual burden per PCCM entity was 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 determined that the May 6, 2016 final rule did 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 finalized our analysis as proposed in this final rule.

6. Less Frequent Collection

As EQR is an annual statutory 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. CMS is required to use information from the state EQR technical reports to satisfy the annual reporting requirements in sections 1139A and 1139B of the Social Security Act.

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

8. Federal Register Notice/Outside Consultation

Federal Register

The 60-day notice published in the Federal Register on February 14, 2019 (84 FR 4075). PRA-related public comments were received. A summary of the comments and our response have been added to this package. As requested by some of the commenters, we added technical changes and edits to the protocols document.

The 30-day notice published in the Federal Register on September 11, 2019 (84 FR 47958).

Outside Consultation

As required by statute (section 1932(c)(2)(A)(iii)), CMS consulted with the National Governors' Association (NGA) during the development of the revised protocols.

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 2018 National Industry-Specific Occupational Employment and Wage Estimates for Direct Health and Medical Insurance Carriers (NAICS 524114) (https://www.bls.gov/oes/current/naics5_524114.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent), and the adjusted hourly wage.

Table 1: Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialist	13-1000	34.63	34.63	69.26
Computer Programmer	15-1131	42.57	42.57	85.14
General and Operations Mgr	11-1021	75.03	75.03	150.06
Office and Administrative Support Worker	43-9000	19.76	19.76	39.52

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 *Information Collection Requirements*

The following information collection requirements and burden estimates replace those that were approved by OMB on June 16, 2017. 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 \$69.26/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 \$11,177.42 (17 hr x \$69.26/hr), annualized to **5.7 hr** and **\$394.78 (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 \$69.26/hr, to conduct the mandatory EQR

activities.

For MCOs and PIHPS, we estimate an aggregate annual state burden of **242,382.63 hr** (511 MCOs and PIHPS x 474.33 [(65 hr x 3 PIP validations) + (53 hr x 3 performance measure validations) + (361 hr / 3 year compliance review)]) and **\$16,787,420.95** (242,382.63 hr x \$69.26/hr) for the first three mandatory EQR-related activities (**Estimate 12.2 (S)**).

For PAHPs, we estimate an aggregate annual state burden of **14,117.53 hr** (41 PAHPs x 344.33 hr [(65 hr x 1 PIP validations) + (53 hr x 3 performance measure validations) + (361 hr / 3 years compliance review)]) and **\$977,780.13** (14,117.67 hr x \$69.26/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 \$69.26/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 **\$2,293,891.20** (33,120 hr x \$69.26 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 **1,559.97 hr** (9 PCCM entities x 173.3 hr [(53 hr x 1 performance measure validations) + (361 hr / 3 years compliance review)]) and **\$108,043.52** (1,560 hr x \$69.26/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 \$69.26/hr by a business operations specialist and half (100 hr) at \$39.52/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 \$69.26/hr by a business operations specialist and half (50 hr) at \$39.52/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 **\$6,086,241.00** [(55,950 hr x \$69.26/hr) + (55,950 hr x \$39.52/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 (\$150.06/hr); 25 percent by a computer programmer (\$85.14/hr); and 55 percent by a business operations specialist (\$69.26/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 \$1,595,611.50 [(17,850 hr x 20 percent x \$150.06/hr) + (17,850 hr x 25 percent x \$85.14/hr) + (17,850 hr x 55 percent x \$69.26/hr)].

- To administer consumer or provider surveys, we estimate 3,750 hr (25 MCOs and PIHPs x 150 hr) and \$335,212.50[(3,750 hr x 20 percent x \$150.06/hr) + (3,750 hr x 25 percent x \$85.14/hr) + (3,750 hr x 55 percent x \$69.26/hr)].
- To validate consumer or provider surveys, we estimate 1,300 hr (26 MCOs and PIHPs x 50 hr) and \$116,207.00 [(1,300 hr x 20 percent x \$150.06/hr) + (1,300 hr x 25 percent x \$85.14/hr) + (1,300 hr x 55 percent x \$69.26/hr)].
- To calculate performance measures, we estimate 8,109 hr (51 MCOs and PIHPs x 159 hr) and \$724,863.51 [(8,109 hr x 20 percent x \$150.06/hr) + (8,109 hr x 25 percent x \$85.14/hr) + (8,109 hr x 55 percent x \$69.26/hr)].
- To conduct PIPs, we estimate 9,945 hr (51 MCOs and PIHPs x 195 hr) and \$888,983.55 [(9,945 hr x 20 percent x \$150.06/hr) + (9,945 hr x 25 percent x \$85.14/hr) + (9,945 hr x 55 percent x \$69.26/hr)].
- To conduct focus studies, we estimate 9,945 hr (51 MCOs and PIHPs x 195 hr) and \$888,983.55 [(9,945 hr x 20 percent x \$150.06/hr) + (9,945 hr x 25 percent x \$85.14/hr) + (9,945 hr x 55 percent x \$69.26/hr)].

In aggregate, the annual state burden for optional EQR-related activities for MCOs and PIHPs is **50,898 hr** (17,850 hr + 3,750 hr + 1,300 hr + 8,109 hr + 9,945 hr + 9,945 hr) and **\$4,587,945.72** [(50,898 hr x 20 percent x \$150.06/hr) + (50,898 hr x 25 percent x \$85.14/hr) + (50,899 hr x 55 percent x \$69.26/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 \$187,719.00 [(2,100 hr x 20 percent x \$150.06/hr) + (2,100 hr x 25 percent x \$85.14/hr) + (2,100 hr x 55 percent x \$69.26/hr)].
- To administer consumer or provider surveys, we estimate 450 hr (3 PAHPs and PCCM entities x 150 hr) and \$40,225.50 [(450 hr x 20 percent x \$150.06/hr) + (450 hr x 25 percent x \$85.14/hr) + (450 hr x 55 percent x \$69.26/hr)].
- To validate consumer or provider surveys, we estimate 150 hr (3 PAHPs and PCCM entities x 50 hr) and \$13,408.50[(150 hr x 20 percent x \$150.06/hr) + (150 hr x 25 percent x \$85.14/hr) + (150 hr x 55 percent x \$69.26/hr)].
- To calculate performance measures, we estimate 954 hr (6 PAHPs and PCCM

entities x 159 hr) and \$85,278.06 [(954 hr x 20 percent x \$150.06/hr) + (954 hr x 25 percent x \$85.14/hr) + (954 hr x 55 percent x \$69.26/hr)].

- To conduct PIPs, we estimate 1,170 hr (6 PAHPs and PCCM entities x 195 hr) and \$104,586.30 [(1,170 hr x 20 percent x \$150.06/hr) + (1,170 hr x 25 percent x \$85.14/hr) + (1,170 hr x 55 percent x \$69.26/hr)].
- To conduct focused studies, we estimate 1,170 hr (6 PAHPs and PCCM entities x 195 hr) and \$104,586.30 [(1,170 hr x 20 percent x \$150.06/hr) + (1,170 hr x 25 percent x \$85.14/hr) + (1,170 hr x 55 percent x \$69.26/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 **\$535,803.66** [(5,994 hr x 20 percent x \$150.06/hr) + (5,994 hr x 25 percent x \$85.14/hr) + (5,994 hr x 55 percent x \$69.26/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 \$69.26/hr for a business operations specialist and 6 hr at \$39.52/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 **\$19,157.64** [(51 MCOs and PIHPs x 2 hr x \$69.26/hr) + (6 hr x \$39.52/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 **\$1,502.56** [4 PAHPs x (2 hr x \$69.26/hr) + (6 hr x \$39.52/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 \$39.52/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 **\$4,347.20** (110 hr x \$39.52/hr) to forward non-duplication-related documentation to the EQROs (**Estimate 12.11 (S)**).

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 \$69.26/hr for a business operations specialist and 6 hr at \$39.52/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 **\$6,385.88** (17 MCOs x

[(2 hr x \$69.26/hr) + (6 hr x \$39.52/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 \$69.26/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 \$1,281.31 (18.5 hr x \$69.26/hr), annualized to **6.2 hr** and **\$429.41 (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 \$69.26/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 \$346.30 (5 hr x \$69.26/hr), annualized to **1.7 hr** and **\$117.74 (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 this 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 \$39.52/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 **233.75 hr** [(561 MCOs, PIHPs, PAHPs, and PCCM entities x 5 requests x 5 min) / 60 min] and **\$9,237.80** (233.75 hr x \$39.52/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 \$69.26/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 \$415.56 (6 hr x \$69.26/hr), annualized to **2.0 hr** and **\$138.52 (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

\$39.52/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 \$118.56 (3 hr x \$39.52/hr), annualized to **1.0** hr and **\$39.52 (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

Table 2: 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	1.00	17.00	69.26	69.26	1,177.42	once	R	5.70	394.78
12.2 (S)	438.358(b)(1)(i)-(iii)	37	511	474.33	242,382.30	69.26	32,852.10	16,787,420.95	annual	R	242,382.63	16,787,420.95
12.3 (S)	438.358(b)(1)(i)-(iii)	12	41	344.33	14,117.53	69.26	23,848.30	977,780.13	annual	R	14,117.53	977,780.13
12.4 (S)	438.358(b)(1)(iv)	37	552	60.00	33,120.00	69.26	4,155.60	2,293,891.20	annual	R	33,120.00	2,293,891.20
12.5 (S)	438.358(b)(2)	5	9	173.33	1,559.97	69.26	12,004.84	108,043.52	annual	R	1,559.97	108,043.52
12.7 (S)	438.358(c)(1)	51	255	199.60	50,898.00	Varies *	17,991.94	4,587,945.72	annual	R	50,898.00	4,491,073.27
12.8 (S)	438.358(c)(1)	51	30	199.80	5,994.00	Varies *	17,860.12	535,803.66	annual	R	5,994.00	528,880.59
12.15 (S)	438.364(a)	37	37	0.50	18.50	69.26	34.63	1,281.31	once	R	6.20	429.41
12.16 (S)	438.364(b)(1)	10	10	0.50	5.00	69.26	34.63	346.30	once	R	1.70	117.74
12.18 (S)	438.370(c)	12	12	0.50	6.00	69.26	34.63	415.56	once	R	2.00	138.52
12.19 (S)	438.370(c)	12	12	0.25	3.00	39.52	9.88	118.56	once	R	1.00	39.52
TOTAL: Reporting		51	1,486	<i>Varies</i>	348,121.30	<i>varies</i>	108,895.93	25,294,224.33	<i>n/a</i>	R	348,088.73	25,188,209.63
12.11 (S)	438.360(b)	40	55	2.00	110.00	39.52	79.04	4,347.20	annual	TPD	110.00	4,347.20
12.17 (S)	438.364(c)(2)	42	2,805	0.0833	233.75	39.52	3.29	9,237.80	annual	TPD	233.75	9,237.80
TOTAL: Third-Party Disclosure		42	2,860	<i>varies</i>	343.75	39.52	82.33	13,585.00	annual	TPD	343.75	13,585.00
TOTAL		51	4,346	<i>varies</i>	348,465.05	<i>varies</i>	108,978.26	25,307,809.33	<i>n/a</i>	<i>n/a</i>	348,432.48	25,201,794.63

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	10,848.91	6,086,241.00	annual	R	111,300	5,947,485.00
12.9 (PS)	438.360(a)	51	51	8	408	varies	375.64	19,157.64	annual	R	408	18,610.92
12.10 (PS)	438.360(a)	4	4	8	32	varies	375.64	1,502.56	annual	R	32	1,459.68
SUBTOTAL: Reporting		561	616	<i>Varies</i>	111,740	<i>varies</i>	11,600.19	6,106,901.20	<i>n/a</i>	R	111,740	5,976,555.60
12.14 (PS)	438.362	17	17	8	136	varies	375.64	6,385.88	annual	TPD	136	6,203.64

<i>SUBTOTAL: Third-Party Disclosure</i>	17	17	8	136	varies	375.64	6,385.88	annual	TPD	136	6,203.64
TOTAL	561	633	varies	111,876	varies	11,975.83	6,113,287.08	n/a	n/a	111,876	5,973,759.24

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

Table 3: Summary of Annual Burden Estimates: Private Sector (PS)

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

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

Table 4: 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	4,346	varies	348,465.05	varies	108,978.26	25,307,809.33	n/a	n/a	348,432.48	25,201,794.63
Private Sector (PS)	561	633	varies	111,876	varies	11,975.83	6,113,287.08	n/a	n/a	111,876	5,973,759.24
TOTAL	612	4,979	varies	460,341	varies	120,954	31,421,096	varies	n/a	460,309	31,175,554

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 \$5,535,271.74. 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 along costs to states through their capitation rates and, applying the estimated weighted (for enrollment) Federal match rate of 58.44 percent (Note: weighted Federal match rate was developed for the May 6, 2016 final rule; a more recent weighted Federal match rate is not available, therefore we continue to apply this estimate.). Therefore, the Federal share for annualized private sector costs is \$3,234,812.80.

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 (\$23,431,058.84), we estimate that 59 percent or \$13,824,324.72 will be eligible for the 75 percent Federal match rate (335 MCOs out of 561 total plans) totaling \$10,368,243.54 and 41 percent or \$9,606,734.13 will be eligible for the 50 percent Federal match rate totaling \$4,803,367.06 (226 PIHPs, PAHPs, and PCCM entities). Therefore, the Federal share for annualized public sector costs is \$15,171,610.60

Total annualized Federal share (private and public sector) is **\$18,406,423.41**.

15. Program or Burden Changes

EQR Protocols

This 2019 information collection request revises the eight existing EQR protocols. The revisions have no impact on any of our currently approved burden estimates. The revisions consist of: (1) consolidating the protocols and associated worksheets and appendices into one document; (2) restructuring and revising the documents to simplify the narrative flow and usability; (3) updating the protocols to include current best practices; and (4) aligning the protocols, appendices, and worksheets with the 2016 final rule. See the Crosswalk for details.

Burden Adjustments

The following burden estimates have been adjusted to account for rounding discrepancies.

Table 5: Burden Adjustments CFR Section	Annualized Hours			Annualized Costs			Reason for Change
	Previous	Revised	Difference	Previous	Revised	Difference	
438.358 EQR-related activities	459,356.60	459,372.13	15.53	\$29,122,175.01	\$ 31,134,574.66	\$2,012,399.65	Corrected rounding discrepancy in hours and updated BLS wages.
438.364 EQR Results	241.6	241.56	-0.04	\$9,044.33	\$99,784.95	\$740.62	Corrected rounding discrepancy in hours and updated BLS wages
TOTAL	426,476	459,614	15	\$29,131,219	\$31,234,360	\$2,013,140	

Base on more current BLS data, additional adjustments have been made to our active wage estimates.

Table 6: Wage Adjustments

Occupation Title	Occupation Code	2017 Adjusted Hourly Wage (\$/hr)	2019 Adjusted Hourly Wage (\$/hr)	Difference (\$/hr)
Business Operations Specialist	13-1000	64.46	69.26	+4.80
Computer Programmer	15-1131	78.32	85.14	+6.82
General and Operations Mgr	11-1021	140.80	150.06	+9.26
Office and Administrative Support Worker	43-9000	36.54	39.52	+2.98

Corrections: External Quality Review Report

Section 12 of the active Supporting Statment that was approved by OMB on June 16, 2017, had erroneously included the following burden changes.

Table 7: Burden Correction

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 (\$)
12.12 (S)	438.360(b)	40	51	474.30	24,189.30	69.26	32,850.02	1,675,350.92	annual	R	24,189.30	1,675,350.92
12.12 (S)	438.360(b)	40	4	344.30	1,377.20	69.26	23,846.22	95,384.87	annual	R	1,377.20	95,384.87
12.13 (PS)	438.360(a)(3)	55	55	150.00	8,250.00	varies	8,158.50	448,717.50	annual	R	8,250	438,487.50
TOTAL		95	110	varies	33,817	varies	64,855	2,219,453	n/a	n/a	33,817	2,209,223

Given that the changes should have been in section 15 of that Supporting Statment, the section 12 budren was underinflated by 33,817 hours. This 2019 iteration corrects 2017 burden estimates by adding 33,817 hours of burden.

Burden Reconciliation

Table 8: Reconciliation of Active and Proposed Burden

	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr) *	Cost (\$) per Response	Total cost (\$)	Frequency	Response Type	Annualized hours	Annualized Costs (\$)
Currently Approved (Active) Burden	612	4,828	Varies	426,509	varies	25,459	27,098,267	Varies	n/a	426,476	27,096,195
Burden Adjustments	No change	41	varies	15	varies	30,640	2,103,376	varies	n/a	15	1,870,136
Burden Corrections	No change	110	varies	33,817	varies	64,855	2,219,453	varies	n/a	33,817	2,209,223
TOTAL (see table 4)	612	4,979	varies	460,341	varies	120,954	31,421,096	varies	n/a	460,308	31,175,554

When considering the 15 hour adjustment and the 33,817 hour correction, this iteration's burden reconciliation consists of adding 33,832 hours (33,817 hr + 15 hr).

16. Publication and Tabulation Dates

The EQR must, at a minimum, result in a detailed annual 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 abstract data from the state-provided EQR technical reports to satisfy annual reporting requirements in sections 1139A and 1139B of the Social Security Act.

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

The expiration date is displayed.

18. Certification Statement

There are no exceptions to the certification statement.