

Supporting Statement - Part A
External Quality Review (EQR) of Medicaid and Children’s Health Insurance Program
(CHIP) Managed Care, EQR Protocols, and Supporting Regulations
CMS-R-305, OMB 0938-0786

Supporting Regulations are located in 42 CFR 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370.

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) of the Act 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)(ii) provides enhanced federal financial participation for these activities. Since 2003, the EQR regulation has undergone numerous revisions and associated collection of information (COI) requests.

This iteration is associated with the changes proposed in our May 3, 2023 (88 FR 28092) NPRM (CMS-2439-P; RIN 0938-AU99). The proposed rule would revise the EQR activities to remove the requirement for PCCM entities to conduct EQR, and to add a new optional activity to support states in conducting quality-related evaluations, as well as a few other technical changes to the way EQR results are reported, and the timing of EQR. We also proposed to require states to maintain a 5-year archive of EQR reports on their websites and that states notify CMS via email or other electronic correspondence when they have posted their EQR reports to their websites, and to share a link.

For States, this iteration would result in an estimated net increase in burden of 20,353 hours, which we estimate to total \$1,942,919 in additional costs. For the private sector, this iteration would result in an estimated net increase in burden of 14,880 hours, which we estimate to total \$870,037 in additional costs.

1. *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 required that the results of the EQR (which are referred to as EQR technical reports) be made publicly available. As proposed under § 438.364(c)(2), the state must post its finalized annual technical report(s) on its website by December 31st of each year. CMS also proposed states submit their EQR technical report(s) to CMS via email by December 31st of each year. § 438.364(c)(2)(ii) requires states to provide the reports to such parties as participating health care providers, enrollees, and potential enrollees of the MCOs, PIHPs or PAHPs upon request.

The BBA also authorized 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 and/or CHIP services must ensure that a qualified EQRO conducts an EQR of each plan each year. The EQR-related activities at 42 CFR 438.358 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; validation of network adequacy. There are six current optional EQR-related activities, and one new optional activity proposed at 42 CFR 438.358(c)(7), 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; assist with the quality rating of MCOs, PIHPs, and PAHPs; and newly proposed activity to assist with certain managed care evaluations required or proposed in 42 CFR Section 438. 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.

2. Use of Information Technology

The information is collected by the states from the managed care plans. The decision as to whether or not collection methods can be improved with newer technology will be up to the states. Presently, states post final reports to their state website. No signature, electronic or written, is required on the document.

We are proposing in CMS 2439-P to require states to maintain a 5-year archive of EQR reports on their websites. We are also proposing to require states notify CMS via email or other electronic correspondence when they have posted their EQR reports to their websites, and to share a link.

3. Duplication of Efforts

The 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.

4. Small Businesses

We estimate that some prepaid ambulatory health plans (PAHPs) are likely to be small entities. Under proposed CMS-2439-P, PCCM entities would not be required under EQR, so the estimates associated with them are no longer applicable. 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 \$41.5 million and offices of physicians or health practitioners with average annual receipts of less than \$12 million. Individuals and state governments are not included in the definition of a small entity.

As of the 2021-2022 EQR reporting cycle, there were a total of 654 Medicaid and CHIP managed care plans (MCPs), including 467 MCOs, 138 PIHPs, and 49 PAHPs participating in the Medicaid and CHIP managed care program and subject to EQR. 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 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 \$41.5 million.

6. Less Frequent Collection

As EQR is an annual statutory requirement, the information must be collected and reported annually. If CMS were not to require states to collect and report 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 Act.

7. Special Circumstances

There is one special circumstance proposed under CM 2439-P, that states must maintain a 5-year archive of EQR reports on their websites. Regarding the remaining special circumstances, 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;
- 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;
- Require a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

Federal Register Notice

Serving as the 60-day notice, the proposed rule (CMS-2439-P; RIN 0938-AU99) published in the Federal Register on May 3, 2023 (88 FR 28092).

As the collection of information request was not posted for public review or submitted to OMB we are making up for that oversight by publishing a standalone 60-day notice in the Federal Register on August 28, 2023 (88 FR 58588). Comments must be received by October 27, 2023.

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 associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Collection of Information Requirements and Associated Burden Estimates

12.1 Wage Estimates

To develop this collection’s cost estimates, we used data from the U.S. Bureau of Labor Statistics’ May 2021 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm). Table 1 presents BLS’ mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 1: National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialist	13-1000	38.64	38.64	77.28
Computer Programmer	15-1250	54.68	54.68	109.36
General Operations Manager	11-1021	55.41	55.41	110.82
Office and Administrative Support Worker	43-9000	18.98	18.98	37.96

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 other indirect 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 and Associated Burden Estimates

The following information collection requirements and burden estimates replace those that were approved by OMB in May 2021 by using the most recently available wage estimates as described in section 12.1. See section 15 of this Supporting Statement for a discussion of this 2022 iteration’s proposed changes.

External Quality Review (§438.350)

There is no burden associated with this section, which describes the required EQR activities for states contracting with MCOs, PIHPs, and PAHPs.

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 or PAHP. 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 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

Section 438.358(b)(1) describes the four mandatory EQR-related activities that must be conducted for each MCO, PIHP, and PAHP. The burden 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.

For the first mandatory EQR-related activity, validation of PIPs, the types of services provided by MCOs, PIHPs, and PAHPs, and the number of PIPs conducted will vary. Based on recent experience, we estimate that each MCO, PIHP, or PAHP will conduct 2 PIPs. We estimate an aggregate annual state burden of **85,020 hr** (654 MCOs, PIHPs, and PAHPs x 130 [65 hr x 2 PIP validations]) and **\$6,570,346** (85,020 hr x \$77.28/hr) (**Estimate 12.2 (S)**).

For the next two mandatory activities, we estimate that each MCO, PIHP or PAHP will calculate 3 performance measures each year. The compliance review will take place every three years and burden is annualized per year. We estimate an aggregate annual state burden of **182,682** (654 MCOs, PIHPs, and PAHPs x 279.33 hr [(53 hr x 3 performance measure validations) + (361 hr /3 years compliance review)]) and **\$14,117,651** (182,682 hr x \$77.28/hr) (**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. We estimate an annual state burden of 60 hr at \$77.28/hr for a business operations specialist to support the validation of network adequacy activity. In aggregate, we estimate a state burden of **39,240 hr** (654 MCOs, PIHPs, and PAHPs x 60 hr) and **\$3,032,467** (39,240 hr x \$77.28 hr) for the validation of network adequacy activity (**Estimate 12.4 (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 an average of 200 hr to prepare the documentation for these four activities, half (100 hr) at \$77.28/hr by a business operations specialist and half (100 hr) at \$37.96/hr by an office and administrative support worker. In aggregate, we estimate annual private sector burden of **130,800 hr** [(654 MCOs, PIHPs, and PAHPs x 200 hr) and **\$7,536,696** [(65,400 hr x \$77.28/hr) + (65,400 hr x \$37.96/hr)] (**Estimate 12.21 (PS)**).

Optional Activities

Section 438.358(c) describes the seven 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; and (7) To assist in evaluations for In Lieu of Services, quality strategies and State Directed Payments that pertain to outcomes, quality, or access to health care services. 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 of MCOs, PIHPs and PAHPs 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 will administer surveys while half (23) 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 (\$110.82/hr); 25 percent by a computer programmer (\$109.36/hr); and 55 percent by a business operations specialist (\$77.28/hr). For the purpose of this estimate, we assume that the 10 percent of affected MCPs operate within 10 percent of states that contract with MCPs (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.

The first set of burden estimates is for optional EQR-related activities conducted by MCOs:

- To validate client-level data, we estimate 16,100 hr (46 MCOs x 350 hr) and \$ 1,481,328.80 [(16,100 hr x 20 percent x \$110.82/hr) + (16,100 hr x 25 percent x \$109.36/hr) + (16,100 hr x 55 percent x \$77.28/hr)].
- To administer consumer or provider surveys, we estimate 3,450 hr (23 MCOs x 150

hr) and \$ \$317,427.60 [(3,450 hr x 20 percent x \$110.82/hr) + (3,450 hr x 25 percent x \$109.36/hr) + (3,450 hr x 55 percent x \$77.28/hr)].

- To validate consumer or provider surveys, we estimate 1,150 hr (23 MCOs x 50 hr) and \$105,809.20 [(1,150 hr x 20 percent x \$110.82/hr) + (1,150 hr x 25 percent x \$109.36/hr) + (1,150 hr x 55 percent x \$77.28/hr)].
- To calculate performance measures, we estimate 7,314 hr (46 MCOs x 159 hr) and \$672,946.51 [(7,314 hr x 20 percent x \$110.82/hr) + (7,314 hr x 25 percent x \$109.36/hr) + (7,314 hr x 55 percent x \$77.28/hr)].
- To conduct PIPs, we estimate 8,970 hr (46 MCOs x 195 hr) and \$825,311.76 [(8,970 hr x 20 percent x \$110.82/hr) + (8,970 hr x 25 percent x \$109.36/hr) + (8,970 hr x 55 percent x \$77.28/hr)].
- To conduct focus studies, we estimate 8,970 hr (46 MCOs x 195 hr) and \$825,311.76 [(8,970 hr x 20 percent x \$110.82/hr) + (8,970 hr x 25 percent x \$109.36/hr) + (8,970 hr x 55 percent x \$77.28/hr)].

In aggregate, the annual state burden for optional EQR-related activities for MCOs is 45,954 hr (16,100 hr + 3,450 hr + 1,150 hr + 7,314 hr + 8,970 hr + 8,970 hr) and \$4,228,135.63 [(45,954 hr x 20 percent x \$110.82/hr) + (45,954 hr x 25 percent x \$109.36/hr) + (45,954 hr x 55 percent x \$77.28/hr)] (**Estimate 12.7 (S)**).

The second set of burden estimates is for optional EQR-related activities conducted by PIHPs, and PAHPs,; we apply the same time, wage, and participation estimates developed for MCOs:

- To validate client level data, we estimate 6,650 hr (19 PIHPs and PAHPs x 350 hr) and \$611,853.20 [(6,650 hr x 20 percent x \$110.82/hr) + (6,650 hr x 25 percent x \$109.36/hr) + (6,650 hr x 55 percent x \$77.28/hr)].
- To administer consumer or provider surveys, we estimate 1,350 hr (9 PIHPs, and PAHPs x 150 hr) and \$124,210.80 [(1,350 hr x 20 percent x \$110.82/hr) + (1,350 hr x 25 percent x \$109.36/hr) + (1,350 hr x 55 percent x \$77.28/hr)].
- To validate consumer or provider surveys, we estimate 450 hr (9 PIHPs and PAHPs x 50 hr) and \$41,403.60 [(450 hr x 20 percent x \$110.82/hr) + (450 hr x 25 percent x \$109.36/hr) + (450 hr x 55 percent x \$77.28/hr)].
- To calculate performance measures, we estimate 3,021 hr (19 PIHPs and PAHPs x 159 hr) and \$277,956.17 [(3,021 hr x 20 percent x \$110.82/hr) + (3,021 hr x 25 percent x \$109.36/hr) + (3,021 hr x 55 percent x \$77.28/hr)].
- To conduct PIPs, we estimate 3,705 hr (19 PIHPs and PAHPs x 195 hr) and \$340,889.64 [(3,705 hr x 20 percent x \$110.82/hr) + (3,705 hr x 25 percent x \$109.36/hr) + (3,705 hr x 55 percent x \$77.28/hr)].

- To conduct focused studies, we estimate 3,705 hr (19 PIHPs and PAHPs x 195 hr) and \$340,889.64 [(3,705 hr x 20 percent x \$110.82/hr) + (3,705 hr x 25 percent x \$109.36/hr) + (3,705 hr x 55 percent x \$77.28/hr)].

To assist in evaluations for In Lieu of Services, quality strategies and State Directed Payments that pertain to outcomes, quality, or access to health care services we estimate an annual State burden of 80 hours per MCO, PIHP and PAHP. In aggregate for Medicaid, the annual State burden to assist in evaluations is 4,640 hours (58 MCOs, PIHPs and PAHPs x 80 hr) at a cost of \$426,917 [(4,640 hr x 0.20 x \$110.82/hr) + (4,640 hr x 0.25 x \$103.36/hr) + (4,640 hr x 0.55 x \$77.28/hr)].

In aggregate, the total annual state burden for optional EQR-related activities for PIHPs and PAHPs (described in §438.310(c)(2)) is **23,521 hr** (6,650 hr + 1,350 hr + 450 hr + 3,021 hr + 3,705 hr + 3,705 hr + 4,640) and **\$2,164,120** [(23,521 hr x 20 percent x \$110.82/hr) + (23,521 hr x 25 percent x \$92.92/hr) + (23,521 hr x 55 percent x \$77.28/hr)] (**Estimate 12.8 (S)**).

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, CHIP, 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 654 MCOs, PIHPs, and PAHPs to substitute information from a Medicare or private accreditation review for the four 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 (65) of MCOs (47), PIHPs (13), and PAHPs (5).

We estimate an annual private sector burden of 2 hr at \$77.28/hr for a business operations specialist and 6 hr at \$37.96/hr for an office and administrative support worker to disclose the necessary documentation to the state each year for a single MCO, PIHP, or PAHP.

In aggregate, we estimate a private sector burden of **472 hr** (59 MCOs and PIHPs x 8 hr) and **\$22,557** [(59 MCOs and PIHPs x 2 hr x \$77.28/hr) + (6 hr x \$37.96/hr)] (**Estimate 12.9 (PS)**).

Under this rule, states may apply the nonduplication provisions to PAHPs. In aggregate, we estimate **48 hr** (6 PAHPs x 8 hr) and **\$15,732** [6 PAHPs x 2 hr x \$77.28/hr) + (6 hr x \$37.96/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 \$37.96/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 **130 hr** (65 MCOs, PIHPs, and PAHPs x 2 hr) and **\$4,935** (130 hr x \$37.96/hr) to forward non-duplication-related documentation to the EQROs (**Estimate 12.11 (S)**).

Additionally, the MCOs, PIHPs, and PAHPs subject to non-duplication will not have to prepare the documentation necessary for the four mandatory EQR-related activities. Further, amendments to § 438.360(a)(1) would remove the requirement that plan accreditation must be from a private accrediting organization recognized by CMS as applying standards at least as stringent as Medicare under the procedures in § 422.158. Eliminating this requirement would simplify the plan accreditation process. We assume that States would apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we anticipate that this provision would offset the burden associated with § 438.358(b)(1)(i) through (iii) for 65 MCOs, PIHPs, and PAHPs (since these activities will no longer be necessary for these 65 plans). Consistent with the estimates used in § 438.358(b)(1)(i) through (iii), we estimate an aggregated offset of annual State burden of minus **26,606 hrs** [(-65 MCOs, PIHPs x 409.33 hr)] and minus **\$2,056,146** (-26,606.45 hr x \$77.28/hr).(**Estimate 12.24 (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 467 MCOs, we estimate that approximately half (234) might provide Medicare services in addition to Medicaid services. Of these 234 MCOs that might potentially provide Medicare services in addition to Medicaid services, we further estimate that state agencies will allow approximately 10 percent (23) of the MCOs to be exempt from the EQR process.

We estimate an annual private sector burden of 8 hr (2 hr at \$77.28/hr for a business operations

specialist and 6 hr at \$37.96/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 **184 hr** (23 MCOs x 8 hr) and **\$8,793** (23 MCOs x [(2 hr x \$77.28/hr) + (6 hr x \$37.96/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 and when 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 and PAHPs is captured in §438.358.

Under §438.364(a)(2), EQR technical reports will include a description and findings related to the new mandatory protocol, Validation of Network Adequacy. We believe that states will amend their EQRO contracts to address this change. We estimate a one- time state burden of 0.5 hr at \$77.28/hr for a business operations specialist to amend the EQRO contract in the estimated 42 states subject to this requirement. 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 22 hr (44 states x 0.5 hr) and \$1,700 (22 hr x \$77.28/hr), annualized to **7.0 hr** and **\$566.67 (Estimate 12.22 (S))**.

Provision § 438.364(a)(2)(iii), would (1) require that the EQR technical reports include “any outcomes data and results from quantitative assessments” for the applicable EQR activities in addition to whether or not the data has been validated, and (2) add the mandatory network adequacy validation activity to the types of EQR activities to which the requirement to include data in the EQR technical report applies. For Medicaid § 438.364, we assume 44 States and 654 MCOs, PIHPs and PAHPs will be subject to the EQR provisions.

We estimate it would take 1 hour at \$77.28/hr for a business operations specialist to describe the data and results from quantitative assessments and 30 minutes at \$37.96/hr for an office clerk to collect and organize data. In aggregate we estimate an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of \$62,954 (654 reports x [(1 hr × \$77.28/hr) + (0.5 hr x \$37.96/hr)]). **(Estimate 12.25 (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 \$37.96/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 or PAHP.

In aggregate, we estimate **273 hr** [(654 MCOs, PIHPs and PAHPs x 5 requests x 5 min) / 60 min] and **\$10,344** (273 hr x \$37.96/hr). (**Estimate 12.17 (S)**).

Reporting

Provision § 438.364(c)(1) shifts the date in which States must finalize their annual EQR technical report. Previously, EQR annual reports had to be posted by April 30th, but under this new provision, EQR technical reports must be posted on the web site required under §§ 438.10(c)(3) and 457.1207 by December 31st of each year. We estimate it would take 1 hour at \$77.28/hr for a business operations specialist and 30 minutes at \$110.82/hr a general operations manager to amend vendor contracts to reflect the new reporting date.

In aggregate, we estimate an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of \$86,779 (654 contracts [(1 hr × \$77.28/hr) + (0.5 hr × \$110.82/hr)]). (**Estimate 12.26 (S)**)

Under § 438.364(c)(2)(i), States must notify CMS within 14 calendar days of posting their EQR technical reports on their quality website and provide CMS with a link to the report. We estimate it would take 30 minutes at \$77.28/hr for a business operations specialist to notify CMS of the posted reports.

In aggregate for Medicaid we estimate an annual State burden of 22 hours (44 States × 0.5 hr) at a cost of \$1,700 (22 hr × \$77.28/hr). (**Estimate 12.27 (S)**)

Provision § 438.364(c)(2)(iii) require States to maintain an archive of at least the previous 5 years of EQR technical reports on their websites. Currently, almost half of States maintain an archive of at least 2 years' worth of EQR reports. Initially, we assume 75 percent of reports completed within the previous 5 years need to be archived on State websites. We estimate it would take 5 minutes (0.0833 hr) at \$77.28/hr for a business operations specialist to collect and post a single EQR technical report to a State website.

In aggregate for § 438.364(c)(2)(iii), we estimate a one-time burden of 204 hours (654 MCOs, PIHPs, and PAHPs yearly reports x 0.75 x 5 years x 0.0833 hr) at a cost of \$15,765 (204 hr × \$77.28/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 68 hours and \$5,255. The annualization divides our estimates by three (3) years to reflect OMB's

likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.28 (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 all states with MCOs, PIHPs, and PAHPs will need to update their EQRO contracts for the new mandatory activity, Validation of Network Adequacy, we estimate that 44 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 \$77.28/hr for a business operations specialist to amend their state's policies and procedures.

In aggregate, we estimate 22 hr (44 states x 0.5 hr) and \$1,700 (22 hr x \$77.28/hr), annualized to **7.0 hr** and **\$566.67 (Estimate 12.23 (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 # (S)	CFR Section	#	Total #	Time per	Total Time (hr)	Labor Rate (\$/hr)	Total cost	Frequency	Response Type	Annualized Time (hr)*	Annualized costs (\$)
		Respondents	Responses	response (hr)			(\$)				
12.2	438.358(b)(1)(i)	44	654	130	85,020	77.28	6,570,346	annual	R	85,020	6,570,346
12.3	438.358(b)(1)(ii)-(iii)	44	654	279	182,682	77.28	14,117,651	annual	R	182,682	14,117,651
12.4	438.358(b)(1)(iv)	44	654	60	39,240	77.28	3,032,467	annual	R	39,240	3,032,467
12.7	438.358(c)(1)	44	230	200	45,954	varies	4,228,136	annual	R	45,954	4,228,136
12.8	438.358(c)(1)	44	152	155	23,521	varies	2,164,120	annual	R	23,521	2,164,120
12.22	438.364(a)	44	44	0.5	22	77.28	1,700	once	R	7	566.67
12.23	438.370(c)	44	44	0.5	22	77.28	1,700	once	R	7	566.67
12.24	438.360(a)(1)	4	-65	-409	-26,606	varies	-2,056,146	annual	R	-26,606	-2,056,146
12.25	438.364(a)(2)(iii)	44	654	1.5	981	varies	62,954	annual	R	981	62,954
12.26	438.364(a)(2)(iii)	44	654	1.5	981	varies	62,954	annual	R	981	62,954
12.27	438.364(c)(2)(iii)	44	44	0.5	22	77.28	1,700	annual	R	22	1,700
12.28	438.364(c)(2)(iii)	44	2453	0.0833	204	77.28	15,765	once	R	68	5,255
<i>Subtotal: Reporting</i>		42	6,172	<i>Varies</i>	352,043	<i>Varies</i>	28,203,347	<i>varies</i>	<i>R</i>	351,877	28,190,570
12.11	438.360(b)	44	65	2	130	37.96	4,935	annual	TPD	130	4,935
12.17	438.364(c)(2)	44	3270	0.0833	273	37.96	10,344	annual	TPD	273	10,344

<i>Subtotal: Third-Party Disclosure</i>	<i>44</i>	<i>3,335</i>	<i>Varies</i>	<i>403</i>	<i>76</i>	<i>15,279</i>	<i>annual</i>	<i>TPD</i>	<i>403</i>	<i>15,279</i>
TOTAL	44	9,507	Varies	352,446	varies	28,218,626	varies	varies	352,280	28,205,849

*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 # (PS)	CFR Section	#	Total #	Time per response	Total Time (hr)	Labor Rate (\$/hr)	Total cost	Frequency	Response Type	Annualized Time (hr)*	Annualized costs (\$)
		Respondents	Responses	(hr)			(\$)				
12.21	438.358(b)(1)	654	654	200	130,800	varies	7,536,696	annual	R	130,800	7,536,696
12.9	438.360(a)	59	59	8	472	varies	22,557	annual	R	472	22,557
12.10	438.360(a)	6	6	8	48	varies	15,732	annual	R	48	15,732
<i>Subtotal: Reporting</i>		<i>654</i>	<i>719</i>	<i>Varies</i>	<i>131,320</i>	<i>varies</i>	<i>7,574,985</i>	<i>annual</i>	<i>R</i>	<i>131,320</i>	<i>7,574,985</i>
12.14	438.362	23	23	8	184	varies	8,793	annual	TPD	184	8,793
<i>Subtotal: Third-Party Disclosure</i>		<i>23</i>	<i>23</i>	<i>8</i>	<i>184</i>	<i>varies</i>	<i>8,793</i>	<i>annual</i>	<i>TPD</i>	<i>184</i>	<i>8,793</i>
TOTAL		654	742	Varies	131,504	varies	7,583,778	annual	varies	131,504	7,583,778

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

Summary of Annual Burden Estimates: State Government and Private Sector

Estimate #	#	Total #	Time per response	Total Time (hr)	Labor Rate (\$/hr)	Total cost	Frequency	Response Type	Annualized Time (hr)*	Annualized costs (\$)
	Respondents	Responses	(hr)			(\$)				
State Government	44	9,507	Varies	352,446	varies	28,218,626	varies	varies	352,280	28,205,849
Private Sector	654	742	Varies	131,504	varies	7,583,778	annual	varies	131,504	7,583,778
Total	698	10,249	Varies	483,950	varies	35,802,404	varies	varies	483,784	35,789,637

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

12.4 Collection of Information Instruments and Instruction/Guidance Documents

CMS External Quality Review (EQR) Protocols (No changes)

13. Capital Costs

There are no capital or maintenance costs.

14. Cost to Federal Government

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

Total annualized private sector costs are \$7,583,014. Consistent with the assumptions used for the private sector match rate in 42 CFR part 438, 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. Therefore, the Federal share for annualized private sector costs is \$4,431,513.

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 and PAHPs by any entity, or on MCOs by non-EQROs.

Of the total annualized public sector costs (\$28,205,849), we estimate that 71 percent or \$20,026,153 will be eligible for the 75 percent Federal match rate (467 MCOs out of 654 total plans) totaling \$15,019,615 and 29 percent or \$8,179,696 will be eligible for the 50 percent Federal match rate totaling \$4,089,848 (187 PIHPs and PAHPs,). Therefore, the Federal share for annualized public sector costs is \$19,109,463.

Total annualized Federal share (private and public sector) is \$23,540,976.

15. Program or Burden Changes

This iteration is associated with the changes proposed in our May 3, 2023 (88 FR 28092) NPRM (CMS-2439-P; RIN 0938-AU99). The proposed rule would revise the EQR activities to remove the requirement for PCCM entities to conduct EQR, and to add a new optional activity to support states in conducting quality-related evaluations, as well as a few other technical changes to the way EQR results are reported, and the timing of EQR. We are also proposing to require states to maintain a 5-year archive of EQR reports on their websites and to require states notify CMS via email or other electronic correspondence when they have posted their EQR reports to their websites, and to share a link.

For the private sector burden, our currently approved annualized time and cost increased. Our annualized total cost increased by \$870,037 (from \$6,713,741 to \$7,583,778). Our annualized total time increased by 14,880 hours from (116,624 hours to 131,504 hours).

For the public sector burden, our currently approved annualized time and cost increased. Our annualized total cost increased by \$1,942,919 (from \$26,262,930 to \$28,205,849). Our annualized total time increased by 20,353 hours (from 331,927 hours to 352,280 hours).

State Burden Estimate Adjustments

		# Respondents			# Responses			Total Hours			Total cost (\$)		
Estimate # (S)	CFR Section	Previous	Revised	Difference	Previous	Revised	Difference	Previous	Revised	Difference	Previous	Revised	Difference
12.2	438.358(b)(1)(i)-(iii)	42	44	2	575	654	79	74,750	85,020	10,270	5,776,680	6,570,346	793,666
12.3	438.358(b)(1)(i)-(iii)	42	44	2	585	654	69	163,410	182,682	19,272	12,628,325	14,117,651	1,489,326
12.4	438.358(b)(1)(iv)	42	44	2	575	654	79	34,500	39,240	4,740	2,666,160	3,032,467	366,307
12.7	438.358(c)(1)	42	44	2	416	230	-186	41,958	45,954	3,996	3,688,024	4,228,136	540,112
12.8	438.358(c)(1)	42	44	2	127	152	25	16,933	23,521	6,588	1,488,377	2,164,120	675,743
12.11	438.358(c)(1)	57	44	-13	57	65	8	114	130	16	4,327	4,935	608
12.17	438.364(c)(2)	42	44	2	2,925	3,270	345	234	273	39	8,873	10,344	1,471
12.22	438.364(a)	42	44	2	42	44	2	7	7	1	541	567	26
12.23	438.370©	42	44	2	42	44	2	7	7	1	541	567	26
TOTAL		57	44	-13	5,344	5,767	423	331,913	376,834	44,921	26,261,848	30,129,132	3,867,284

Private Sector Burden Estimate Adjustments

		# Respondents			# Responses			Total Hours			Total cost (\$)		
Estimate # (PS)	CFR Section	Previous	Revised	Difference	Previous	Revised	Difference	Previous	Revised	Difference	Previous	Revised	Difference
12.21	438.358(b)(1)	575	654	79	575	654	79	115,000	130,800	15,800	6,626,300	7,536,696	910,396
12.9	438.360(a)	54	59	5	54	59	5	432	472	40	20,645	22,557	1,912
12.10	438.360(a)	3	6	3	3	6	3	24	48	24	1,147	15,732	14,585
12.14	438.362	21	23	2	21	23	2	168	184	16	8,029	8,793	764
TOTAL		575	654	79	633	742	89	115,624	131,504	15,880	6,656,121	7,583,778	927,657

Removal of State Burden Estimates

Estimate # (S)	CFR section	# Respondents	# Responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Total cost (\$)	Frequency	Response Type	Annualized hours	Annualized Costs (\$)
12.20	438.358(b)(1)(iv)	42	42	1	42	77.28	3,246	once	R	14	1,082
TOTAL		42	(42)	1	(42)	77.28	(3,246)	once	R	(14)	(1,082)

Removal of Private Sector Estimates

Estimate # (S)	CFR section	# Respondents	# Responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Total cost (\$)	Frequency	Response Type	Annualized hours	Annualized Costs (\$)
12.6	438.358(b)(2)	10	10	100	1,000	varies	57,620	once	R	1,000	57,620
TOTAL		10	(10)	100	(1,000)	varies	(57,620)	once	R	(1,000)	(57,620)

Addition of State Burden Estimates

Estimate # (S)	CFR section	# Respondents	# Responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Total cost (\$)	Frequency	Response Type	Annualized hours	Annualized Costs (\$)
12.24	438.360(a)(1)	4	-65	-409	-26,606	varies	2,056,146	annual	R	-26,606	-2,056,146
12.25	438.364(a)(2)(iii)	44	654	1.5	981	varies	62,954	annual	R	981	62,954
12.26	438.364(a)(2)(iii)	44	654	1.5	981	varies	62,954	annual	R	981	62,954
12.27	438.364(c)(2)(iii)	44	44	0.5	22	77.28	1,700	annual	R	22	1,700
12.28	438.364(c)(2)(iii)	44	2453	0.0833	204	77.28	15,765	once	R	68	5,255
Total		44	3,740	varies	(24,418)	varies	2,199,519	varies	R	(24,554)	(1,923,283)

Summary of Changes

State Burden	# Respondents	# Responses	Annualized hours	Annualized Costs (\$)
Adjustments	(13)	423	44,921	3,867,284
Additions	44	3740	(24,554)	(1,923,283)
Removal	42	(42)	(14)	(1,082)
TOTAL	44	4,121	20,353	1,942,919

Private Sector Burden	# Respondents	# Responses	Annualized hours	Annualized Costs (\$)
Adjustments	79	89	15,880	927,657
Removal	10	(10)	(1,000)	(57,620)
TOTAL	79	79	14,880	870,037

	# Respondents	# Responses	Annualized hours	Annualized Costs (\$)
State Burden	44	4,121	20,353	1,942,919
Private Sector Burden	79	79	14,880	870,037
TOTAL	79	4,200	35,233	2,812,956

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 or PAHP;
- 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, or PAHP, with respect to timeliness, access, and quality of the health care services furnished to Medicaid and CHIP beneficiaries;
- 4) Recommendations for improving the quality of the services furnished by each MCO, PIHP or PAHP, 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, or PAHPs 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, or PAHP 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.

17. Expiration Date

We will display OMB's expiration date.

18. Certification Statement

There are no exceptions to the certification statement.