

Supporting Statement-Part A

Supporting Statement for External Quality Review (EQR) of Medicaid Managed Care Organizations (MCOs) and Supporting Regulations in §438.352, §438.360, §438.362, and §438.364. (CMS-R-305/OMB #: 0938-0786)

A. Background

On December 1, 1999, we published a proposed rule concerning external quality review (EQR) of Medicaid managed care organizations (MCOs). (64 FR 67223) The EQR regulation implemented (1) section 1932(c)(2) of the Social Security Act (the Act), which was enacted in section 4705(a) of the Balanced Budget Act of 1997 (BBA), and (2) section 1903(a)(3)(C)(ii) of the Act, which was enacted in section 4705(b) of the BBA. Under section 1932(c)(2) each contract between a state Medicaid agency (state agency) and an MCO must provide for an annual EQR of the quality outcomes, the timeliness of, and access to, the services for which the MCO is responsible under the contract. Section 1903(a)(3)(C) provides enhanced matching for these activities. On January 24, 2003, we published the final EQR rule.

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

The annual external review is to be conducted by an independent entity that meets the qualifications set forth in the final rule, using protocols also provided for in that rule.

In addition, the BBA provisions allow state agencies to exempt certain Medicare MCOs from all EQR requirements or from particular review activities that would duplicate review activities conducted as part of a Medicare MCO's external review or accreditation processes.

The BBA provisions require that the results of the EQR be made available to participating health care providers, enrollees and potential enrollees of the MCO, and also authorize the payment of enhanced Federal financial participation at the 75 percent rate for the administrative costs of EQRs that are conducted by approved entities.

In addition, the rule extended 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.

The Paperwork Reduction Act (PRA) approval of the protocols expired on June 30, 2009 and a PRA renewal package was filed prior to that date. CMS, however, was aware of the need to revise the protocols at a later time due to their anticipated use in newly- required Children's Health Insurance Program (CHIP) EQR reviews. Consequently, on March 13, 2009, a notice was placed in the Federal Register soliciting comments on the protocols. While only two entities replied, they had twenty-five comments. CMS has reviewed and responded to the comments and the responses will be provided to the workgroup which will consider revision of the protocols.

B. 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.

Sections 1932(c)(2)(B) and (C) allow for states, at their option and in accordance with the requirements in our proposed rule, to allow for the nonduplication of accreditation and the exemption of EQR.

2. Information Users

The regulation requires that the state agency provide to the EQRO information obtained through methods consistent with the protocols specified by CMS. This information is generated by an EQRO, other state contractor, or the state and is used by the EQRO to determine the quality of care furnished by an MCO/PIHP.

The regulation extends the availability of the results of EQR to the general public. 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.

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 that access and timeliness of quality services are provided by the MCO/PIHP. Thus, information from the accreditation and Medicare review activities must be made available to the states agency in order for the state agency to use the information in its oversight of these organizations.

3. Use of Information Technology

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

4. Duplication of Efforts

Consistent with §438.360, these information collection requirements do not duplicate similar information collections. Rather, the intent of §438.360 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 with whom they contract.

5. Small Businesses

These information collection requirements do not affect small businesses.

6. Less Frequent Collection

As EQR by statute is an annual requirement, the information must be collected annually. If CMS were not to require states to collect this information annually, the states would be in violation of the law.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

CMS published in the March 13, 2009 Federal Register a Request for Comments on the nine External Quality Review (EQR) Protocols used in doing EQR reviews in Medicaid managed care programs.

The EQR proposed rule was published on December 1, 1999 and allowed for a 60-day comment period. The EQR final rule published on January 24, 2003 provides responses to all of the public comments received on the proposed rule, as well as responses to the public comments received on the protocols.

As statutorily mandated, CMS consulted with state Medicaid agencies as well as other stakeholders such as advocacy organizations and other experts in quality

improvement. In addition, more specific state input was obtained from the Medicaid Managed Care and Quality Technical Advisory Groups in the fall of 1998 through the spring of 1999 on an as needed basis to discuss implementation issues.

We published a notice in the Federal Register on November 23, 2001, to give the public a 60-day period in which to comment. The basic purpose was to afford the public an opportunity to comment on the protocols. We addressed the comments received in response to this Federal Register notice in the final EQR rule published on January 24, 2003.

A 60-day Federal Register notice was published on 1/20/2006. The protocols were approved without change.

The protocols were due to expire June 30, 2009, but a PRA renewal package was filed. The enactment of the Children's Health Insurance Reauthorization Act on February 6, 2009 has resulted in new EQR requirements for States. State Children's Health Insurance Programs that utilize managed care organizations or prepaid health insurance plans will now also be required to comply with the managed care requirements for external quality reporting. Consequently, while renewing the old protocols, CMS also filed a notice in the Federal Register on March 13, 2009 to solicit comments on the protocols for use in a contemplated protocol revision in 2010.

In order to extend OMB approval for the current protocols, CMS is submitting the existing EQR protocols for approval with the following actions planned for the next two years:

- 1) Establish a CMS workgroup to evaluate the impact of the new Children's Health Insurance Reauthorization Act on State Medicaid and CHIP programs and consider revisions to the EQR protocols to address new State reporting needs. This workgroup will consider the comments received after the March 13, 2009 Federal Register request for comments and CMS responses in their evaluation.
- 2) Solicit an outside vendor to complete revision of the protocols by June 30, 2010.
- 3) Issue a 60-day Federal Register Notice for public comment on proposed changes to the CMS EQR protocols.
- 4) Review public comments and complete final revisions of the CMS EQR Protocols by October 1, 2010.
- 5) Issue a 30-day Federal Register Notice for public comment on Final proposed CMS EQR Protocols in November 1, 2010.
- 6) Issue the final protocols to be effective January 1, 2011.

9. Payment/Gift to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected as a result of §438.352, §438.360, §438.362, and §438.364 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

§ 438.352 (EQR Protocols) - The State must ensure that information is provided to the EQRO, which is obtained through methods consistent with three of the nine protocols established under this section. As published in our final rule, only three protocol activities are specified as mandatory activities. These are (1) validation of performance improvement projects (2) validation of performance measures and (3) determination of compliance with certain standards established by CMS and states. In addition, if a state, at its option, wishes to provide additional information to its EQRO, and to have CMS provide 75% Federal Financial Participation in the costs of producing this information, then the additional information must be produced through activities identified as optional activities in our January 24, 2003 final rule and also must be produced in a manner consistent with (as opposed to identical to) the protocols for these six optional activities. These six optional activities are (1) validation of client level data such as claims and encounters (2) administration of a survey (3) validation of a survey (3) calculation of performance measures (4) conduct of performance improvement projects and (6) conduct focused studies of quality of care.

The burden associated with this requirement is the time and effort for an EQRO or other state contractor to conduct and document the findings of the three mandatory activities -- the validation of performance improvement projects conducted by the MCO/PIHP, the validation of performance measures calculated by the MCO/PIHP, and a review of MCO/PIHP compliance with structural and operational standards. Each of these activities will need to be conducted on the 329 MCOs and 129 PIHPs that we estimate are currently providing Medicaid services. The types of services provided by these managed care entities and the number of performance improvement projects conducted and performance measures calculated will vary. In addition, each of the 40 states, DC, and Puerto Rico will choose to do none, some or all of the five optional activities.

We interviewed 4 EQROs who had reviewed MCOs/PIHPs in 16 mandatory or voluntary managed care programs in 8 states. Based on the information provided by the 4 EQROs, we confirmed that the hours and costs to conduct these activities do vary. The information provided includes: 1) it takes 25 - 138 hours at a cost of \$2,000 - \$10,000 to validate a performance improvement project conducted by an MCO/PIHP; 2) it takes 12 - 202 hours at a cost of \$1,200 to \$7,000 to validate a performance measure calculated by an MCO/PIHP; and it takes 200 - 800 hours at a cost of \$11,000 - \$49,000 to review for MCO/PIHP compliance with structural and operational standards. Based on the submitted information it takes an average of 65, 53, and 361 hours, respectively, to conduct the above mandatory EQR activities. Therefore, the average total burden associated with this requirement is 479 hours x 458 entities (329 MCOs + 129 PIHPs) = **219,382 hours**.

For the optional EQR activities -- validation of client level data (such as claims and encounters), administration or validation of consumer or provider surveys, calculation of performance measures, conduct of performance improvement projects, and conduct of focused studies -- we have no data to estimate the hours associated with how long it will take to conduct these activities. We, therefore, estimate that it will take 350 hours to validate client level data and 50 hours to validate consumer or providers surveys. We estimate it will take three times as long to calculate performance measures as it takes on average to validate (159 hours (3 x 53)) and three times as long to conduct performance improvement projects and focused studies as it takes on average to validate performance improvement projects (195 hours (3 X 65)). We also estimate that it will take three times as long to administer a consumer or provider surveys than it takes to validate a survey (150 hours (3 X 50)).

Based on state reported data we know that of the 42 programs that were capitated programs (MCOs or PIHPs) in 2008, 29 (69%) had their EQROs validate MCO/PIHP encounter data, 18 (43%) had their EQRO administer or validate consumer or provider surveys, 12 (29%) had their EQRO calculate performance measures, 16 (38%) had their EQRO conduct performance improvement projects, and 32 (76%) had their EQRO conduct focused studies. Using the aforementioned percentages and applying them to the number of MCOs and PIHPs, we estimate that states will contract with their EQROs to validate the encounter data of 316 MCOs/PIHPs, administer or validate consumer or provider surveys of 197 MCOs/PIHPs, calculate performance measures of 133 MCOs/PIHPs, conduct performance improvement projects of 174 MCOs/PIHPs, and conduct focused studies of 348 MCOs/PIHPs.

We, therefore, estimate the average total burden presently associated with conducting each optional EQR activity as follows:

- validating client level data 350 hours x 316 MCOs/PIHPs = **110,600 hours**
- validate consumer or provider surveys 50 hours x 98 MCOs/PIHPs (1/2 of 197 MCO/PIHPs that administered or validated surveys) = **4,900 hours**

- administer consumer or provider surveys 150 hours x 99 MCOs/PIHPs (1/2 of 197 MCO/PIHPs that administered or validated surveys) = 14,850 hours
- calculate performance measures 159 hours x 133 MCOs/PIHPs = 21,147 hours
- conduct performance improvement projects 195 hours x 174 MCOs/PIHPs = 33,930 hours
- conduct focused studies 159 hours x 348 MCOs/PIHPs = 55,332 hours

The burden estimate associated with this requirement also includes the time and effort for an MCO/PIHP to prepare the information necessary for the EQRO to conduct the three mandatory activities. We estimate that it will take each MCO/PIHP 160 hours to prepare this documentation

§438.360 (Nonduplication of mandatory activities) - In order to avoid duplication, the state agency may exempt an MCO/PIHP from conducting mandatory EQR activities if specified conditions are met. To demonstrate compliance with these requirements an MCO/PIHP must provide to the state agency all the reports, findings, and other results of the Medicare or private accreditation review. The burden associated with these requirements is the time and effort for an MCO/PIHP to disclose all the reports, findings, and other results of the Medicare or private accreditation review to the state agency. Of the 329 MCOs and 129 PIHPs providing Medicaid services, approximately 122 are Medicaid only MCOs. We believe that there is the potential for states to allow the remaining 336 MCOs/PIHPs to take advantage of the non-duplication provision and that these MCOs will be required to disclose the necessary information to each state agency. We further estimate that it will take each MCO 8 hours to disclose the necessary documentation to the state. Therefore, the total burden associated with this requirement is 336 MCOs/PIHPs x 8 hours = 2688 annual burden hours. This section also requires that a state agency provide all the reports, findings, and other results of the Medicare or private accreditation review to the appropriate EQR organization (EQRO). We estimate that it will take, on average, 8 hours per MCO/PIHP for a state to disclose the necessary documentation to the appropriate EQRO. The total annual burden associated with this requirement is 2688 hours.

§438.362 (Exemption from EQR) - Each year, exempted MCOs/PIHPs must provide to the state agency the most recent Medicare review findings reported to the MCO/PIHP by CMS or its agent. This information must include 1) all data, correspondence, information, and findings pertaining to the MCOs/PIHPs compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities; 2) all measures of the MCOs/PIHPs performance; and 3) the findings and results of all performance improvement projects pertaining to Medicare enrollees. If an exempted MCO/PIHP has been reviewed by a private accreditation organization and the survey results have been used to either fulfill certain requirements for Medicare external review under 42 CFR part 422, subpart D or to deem compliance with Medicare requirements as provided in §422.156, the

MCO/PIHP must submit a copy of all findings pertaining to its most recent accreditation survey to the state agency. These findings shall include accreditation survey results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

We estimate, of the approximately 202 MCOs that potentially may provide Medicare services in addition to Medicaid services, state agencies will allow for approximately 10 percent of the MCOs to be exempt from the EQR requirement. We further estimate that it will take each MCO 8 hours to prepare and submit the necessary documentation to the state agency. Therefore, the total burden associated with this requirement is 10% of 202 MCOs x 8 hours = 160 annual burden hours.

§438.364 (EQR results) -Each EQRO is required to submit to the state agency a detailed technical report that describes for each mandatory and optional activity undertaken for the EQR, the objectives, technical methods of data collection and analysis, data obtained, conclusions drawn from the data, and the manner in which the conclusions were drawn as to the quality of the care furnished by the MCO/PIHP. In addition, the report must include: 1) a detailed assessment of each MCO's/PIHP's strengths and weaknesses with respect to the timeliness, access, and quality of health care services furnished to Medicaid beneficiaries; 2) recommendations for improving the quality of health care services furnished by each MCO/PIHP; 3) as the state agency determines methodologically appropriate, comparative information about all MCOs/PIHPs, and 4) an assessment of the degree to which each MCO/PIHP has addressed effectively the recommendations for quality improvement, as made by the EQRO during the previous year's EQR. The burden associated with this requirement is the time and effort for an EQRO to submit to a state agency a detailed technical report for each EQR conducted. It is estimated that it will take an EQRO 200 hours to prepare and submit the necessary documentation to the state agency. Therefore, the total burden associated with this requirement is 458 technical reports (329 MCOs + 129 PIHPs) x 200 hours = 91,600 annual burden hours.

This section also requires each state agency to provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO/PIHP, beneficiary advocate groups, and members of the general public.

The burden associated with this requirement is the time and effort for a state agency to disclose copies of a given technical report to interested parties. We estimate that on average, it will take a state agency 8 hours to disclose the required information. Therefore, the total burden associated with this requirement is 329 MCOs + 129 PIHPs x 25 requests per MCO or PIHP x 8 hours = 91,600 annual burden hours.

The total number of hours that these activities take presently is 648,887. These hours represent the time spent providing EQRO services to the 33,427,582 Medicaid members presently in Medicaid managed care. Given that CHIPRA will add approximately 4.3 million CHIP managed care beneficiaries to the present Medicaid number, it is probable that this number will escalate to roughly 733.3 thousand hours as EQR studies of CHIP managed care entities are added.

The total cost of state and federal share of EQRO contracts in 2007 was approximately 52 million dollars (39 million federal and 13 million state). Of course, there are enormous variances between the states due to program differences and the range of actual costs runs from about \$500,000 to over five million dollars. Adjusting this number for the CHIPRA change, we can expect total costs to increase to about 58.75 million dollars. Given that it is not clear at this point whether the 75% enhanced federal match will be applicable to CHIP EQR, it is not possible to estimate with certainty the federal and state components of the new total number.

13. Capital Costs

There are no capital or maintenance costs.

14. Cost to Federal Government

Of the 52 million spent in 2007, 75% or 39 million was paid by the federal government. Of the estimated 58.75 million to be spent after the CHIPRA changes, the federal share if held steady at 75% would be about 44 million, but will likely be less than that number as it is doubtful that the 75% enhanced match will apply to CHIP EQR

15. Program or Burden Changes

There are no changes.

16. Publication and Tabulation Dates

External Quality Review will produce, at a minimum, the following information: A detailed technical report that describes the following for each activity conducted: 1) the objectives; 2) the technical methods of data collection and analysis; 3) the data obtained; and 4) the conclusions drawn from the data. In addition, the report must also describe the manner in which the data from all activities conducted were aggregated and analyzed, and how the conclusions were drawn as to the quality of the care furnished by the MCO/PIHP. The report will also include a detailed assessment of each MCO's/PIHP's strength and weaknesses with respect to timeliness, access, and quality of the health care

services furnished to Medicaid enrollees; the recommendations for improving the quality of the services furnished by each MCO/PIHP; comparative data about all MCOs/PIHPs, as determined appropriate by the state agency; and an assessment of the degree to which each MCO/PIHP addressed effectively the recommendations for quality improvement, as made by the EQRO during the previous year's EQR. The report will be submitted by the contracting EQRO to the state that will provide this information upon request.

17. Expiration Date

These information collection requirements do not lend themselves to an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.