

Supporting Statement - Part A
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

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; these were reviewed and responses included in the preamble to the final rule.

The annual external quality review is to be conducted by an independent entity that meets the qualifications set forth in the final rule, using protocols (or methods consistent with the 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 2003 final 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 was renewed without change in 2006 and in 2009. At the time of the 2009 renewal, CMS was aware of the need to revise the protocols at a later time due to their use in the then newly-required Children's Health Insurance Program (CHIP) EQR reviews.

On July 1, 2010, CMS entered a contract with Provider Resources, Inc. (PRI) to revise the EQR Protocols for the first time since they were drafted in 2002. The revision was financed by CHIPRA funds and a principal reason for the revision was to add CHIP material to what had been designed for use in the Medicaid program. The revision also addressed numerous changes in law and quality practices beyond just the changes related to CHIPRA, including recommendations to voluntarily align with quality reporting opportunities under HITECH provisions of the American Recovery and Reinvestment Act of 2009, and the Affordable Care Act of 2010. The contract concluded at the end of 2010 and PRI delivered the revisions to CMS. The revised EQR Protocols received OMB approval in September 2012 for a three-year period, which expires September 30, 2015.

At this time, the Division of Quality, Evaluation and Health Outcomes (DQEHO) is submitting the unchanged Protocols to OMB for another three year approval.

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.

Section 2103(f) requires managed care providers in the CHIP Program to be subject to the same type of EQR which has been applied to Medicaid managed care providers.

2. Information Users

The law 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 that is not an MCO or PIHP, or the state, and is used by the EQRO to determine the quality of care furnished by an MCO.

The regulation extends the availability of the results of EQR to the general public. This allows Medicaid/CHIP 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/CHIP MCOs.

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. Thus, information from the accreditation and Medicare review activities must be made available to the states agency in order for the state agency to use the information in its oversight of these organizations.

3. Use of Information Technology

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

4. Duplication of Efforts

These information collection requirements do not duplicate similar information collections. Rather, the intent is to provide states with an option to not have to duplicate Medicare or private accreditation review activities, thus enabling the state to minimize duplication of requirements placed on MCOs 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. Information from the State EQR Reports is also used to inform the Annual Secretary's Report on Quality of Care for Children, required by CHIPRA Section 401(c)(B) (Annual State Reports Regarding State-Specific Quality of Care Measures Applied Under Medicaid or CHIP) and the Annual Secretary's Report on Quality of Care for Adults, required by Affordable Care Act Section 2701 (Adult Health Quality Measures).

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

2015

The 60-day Federal Register notice published on December 19, 2014 (79 FR 75816). A comment was received which contained only a single word, "suggestion."

In our attempt to gather additional information, CMS reached out to the commenter via email, but no response was received. The comment and our response have been added to this package.

Prior Iterations

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. As statutorily mandated, CMS consulted with state Medicaid agencies as well as other stakeholders such as advocacy organizations and other experts in quality improvement regarding the development of the EQR protocols. This was done at the time of the original drafting of the Protocols in 2002 and was also part of the contract requirements with PRI as they drafted the revisions in 2010. Comments obtained from the March 13, 2009, Federal Register notice, were used by PRI in the revision process. We also solicited public comments on the revised Protocols during the 60-day (February 17, 2012) and 30-day (May 31, 2012) comment periods prior to OMB approval of the revised Protocols in September 2012.

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

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2014 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly	Fringe Benefit	Adjusted Hourly
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		Wage (\$/hr)	(\$/hr)	Wage (\$/hr)
Business Operations Specialist	13-1000	33.69	33.69	67.38
General and Operations Manager	11-1021	56.35	56.35	112.70

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Estimated Burden

(EQR Protocols) - The State must ensure that information is provided to the EQRO, which is obtained either through the protocols established under this section, or through methods consistent with these protocols. As has been the situation since promulgation of the 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. The other five protocol activities are specified as optional activities. These are: (1) validation of client level data such as claims and encounters (2) administration and/or validation of a survey (3) calculation of performance measures (4) conduct of performance improvement projects and (5) conduct focused studies of quality of care. If a state, at its option, wishes to provide additional information to its EQRO, and to have CMS provide 75 percent Federal Financial Participation in the costs of producing this information, then the additional information must be produced through these optional activities in a manner consistent with (as opposed to identical to) the five associated protocols.

The burden associated with this requirement is the time and effort for the state, its contractor that is not an MCO/PIHP, and/or an EQRO to conduct and document the findings of the three mandatory activities - the annual validation of performance improvement projects conducted by the MCO/PIHP, the annual validation of performance measures calculated by the MCO/PIHP, and, once every three years, a review of MCO/PIHP compliance with structural and operational standards. 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 41 states, DC, and Puerto Rico will choose to do none, some or all of the five optional activities. This is also the case for the 30 CHIP programs.

Based on state reported data we know that of the 43 programs that were Medicaid managed care programs (MCOs or PIHPs) in 2008, 29 (69 percent) had their EQRO validate MCO/PIHP encounter data, 18 (43 percent) had their EQRO administer or

validate consumer or provider surveys, 12 (29 percent) had their EQRO calculate performance measures, 16 (38 percent) had their EQRO conduct performance improvement projects, and 32 (76 percent) had their EQRO conduct focused studies. The total number of hours required for these activities for 40 Medicaid managed care states was 237,503 hours, or 5,938 hours per state.

Now estimating that there are 43 states with Medicaid managed care and 33 states with CHIP managed care, we estimate a total annual burden of **451,288 hr** [(43 Medicaid managed care states + 33 CHIP managed care states) x 5,938 hr/state).

We estimate half these hours (2,969 hr) at \$33.69/hr for a Business Operations Specialist and half these hours (2,969) at \$112.70/hr for a General and Operations Manager.

Estimating 43 states with Medicaid managed care and 33 states with CHIP managed care, we estimate \$33,032,025 [(225,644 hr x \$33.69/hr) + (225,644 x \$112.70/hr)]. Assuming these costs are matched at the 75 percent rate, the Federal share would be \$24,774,019 while the state share would be approximately **\$8,258,006**. However, given that EQR-related activities are not always conducted by an EQRO and thus are not always eligible for the 75 percent rate, and the variations in CHIP match rates, actual Federal share could be lower.

13. Capital Costs

There are no capital or maintenance costs.

14. Cost to Federal Government

Of the estimated \$33,032,025 annual costs for EQR for Medicaid and CHIP managed care programs, the Federal share if held steady at 75 percent would be about **\$24,774,019**, but will likely be slightly less than that number given: (1) not all EQR-related activities will be conducted by an EQRO and thus eligible for the 75 percent rate, and (2) the CHIP EQR Federal match will be paid at the regular CHIP match for that State (65 percent - 85 percent).

15. Program or Burden Changes

There are no changes to the Protocols or rules.

Adjustments have been made to account for: (1) the number of respondents, the type of respondents, annual responses, and annual hour burden, and (2) updated BLS job titles and wages.

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) Objectives;
- 2) Technical methods of data collection and analysis;
- 3) 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.