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. 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. OMB approved this PRA for a three year renewal in 2009. However, at that time, CMS was aware of the need to revise the protocols at a later time due to their use in the 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 updated numerous changes in law and quality practices beyond just the changes for CHIP, 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. At this point, The Division of Quality, Evaluation and Health Outcomes (DQEHO) is submitting the revised 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, 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.

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. Another Federal Register Notice soliciting comments on the revisions will be published as part of this PRA process in 2011.

   As statutorily mandated, CMS consulted with state Medicaid agencies as well as other stakeholders such as advocacy organizations and other experts in quality improvement. This was done at the time of the original revisions in 2002 and was also part of the contract requirements with PRI as they drafted the revisions in 2010. We also solicited public comments during the 60 day comment period under Federal Register notice

published on February 17, 2012 as part of this PRA process (Vol. 77, No. 33, pages 9661-9662).

PRA authority for the existing protocols is due to expire October 31, 2012. We are filing this new PRA package for the revised Protocols so that they can replace the existing Protocols before their PRA authority ends. 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. Comments obtained from the March 13, 2009, Federal Register notice, were used by PRI in the revision process.

In order to obtain OMB approval for the revised protocols, CMS is now submitting them for approval. The 60-day Federal Register notice published on February 17, 2012 (77 FR 9661). Comments were received and our response has been added to this package.

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

(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 in the previous Medicaid EQR process, 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 percent Federal Financial Participation in the costs of producing this information, then the additional information must be produced through activities identified as optional activities in 42 CFR 438.358 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. 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 anticipate that we will receive 30 new CHIP EQR reports in addition to the 40 Medicaid State reports that we currently receive annually.

Based on state reported data we know that of the 42 programs that were Medicaid managed care programs (MCOs or PIHPs) in 2008, 29 (69 percent) had their EQROs 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 that these activities take presently is 237,503 hours. The average cost of an hour of EQRO time is $100. These hours represent the time spent producing 40 EQRO reports for Medicaid members presently in Medicaid managed care. Given that CHIPRA will add 30 reports on CHIP managed care beneficiaries to the present Medicaid number, it is probable that the total hours spent on the 70 reports will escalate to 415,643 hours as EQR studies of CHIP managed care entities are added.

The total cost of state and Federal share of EQRO contracts in 2010 was approximately $23,750,337 dollars ($17,857,396 Federal and $5,892,941 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 $41,564,337.

13. Capital Costs

There are no capital or maintenance costs.

14. Cost to Federal Government

Of the $23,750,337 spent in 2010, 75 percent or $17,857,396 was paid by the Federal government. Of the estimated $41,564,337 to be spent after the CHIPRA changes, the Federal share if held steady at 75 percent would be about $31,173,253, but will likely be slightly less than that number as CHIP EQR Federal match will be paid at the regular CHIP match for that State (65 percent - 85 percent).

15. Program or Burden Changes

Burden changes attributable to the CHIPRA changes will result in roughly 178,140 additional hours.

Adjustments have been made to account for mathematical errors in regard to the number of respondents, the type of respondents, annual responses, and annual hour burden.

Protocols have been revised as documented in this package's Crosswalk. Some of those changes are explained in this package's Response to Comments. The net burden change from the revisions to these protocols is zero.

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.