based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

**DATES:** Written comments must be received on or before January 3, 2000.

**ADDRESSES:** Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection (mail code CAA), U.S. Environmental Protection Agency, Region I, One Congress Street, Suite 1100 Boston, MA 02114–2023. Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA; Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, S.W., (LE–131), Washington, D.C. 20460; and the Bureau of Air Management, Department of Environmental Protection, State Office Building, 79 Elm Street, Hartford, CT 06106–1630.

**FOR FURTHER INFORMATION CONTACT:** Jeff Butensky, Environmental Planner; (617) 918–1665; butensky.jeff@epa.gov.

**SUPPLEMENTARY INFORMATION:** For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: November 10, 1999.

**John P. DeVillars,**

*Regional Administrator, Region I.*

[FR Doc. 99–31046 Filed 11–30–99; 8:45 am]

**BILLING CODE 6560–50–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### 42 CFR Parts 433 and 438

**[HCFA–2015–P]**

**RIN 0938–AJ06**

## Medicaid Program; External Quality Review of Medicaid Managed Care Organizations

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would establish requirements and procedures for external quality review (EQR) of Medicaid managed care organizations (MCOs). The rule would implement 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 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.

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

In addition, these 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.

These 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.

**DATES:** *Comment date.* Comments will be considered if we receive them at the appropriate address, as provided below no later than 5 p.m. on January 31, 2000.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2015–P, P.O. Box 7517, Baltimore, MD 21207–0517.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, MD.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–2015–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690–7890).

**FOR FURTHER INFORMATION CONTACT:** Sharon Gilles, (410) 786–1177.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In 1965, the Congress passed Title XIX of the Social Security Act (the Act) which established the Medicaid program. Under this title, we pay Federal financial participation (FFP) to State Medicaid agencies (State agencies) to assist in the costs of health care for low-income pregnant women, families, and aged, blind and disabled individuals. The Medicaid program is administered by State agencies subject to Federal statutory and regulatory requirements, which are implemented in accordance with a ''State plan'' that must be approved by the Health Care Financing Administration (HCFA).

In the early years of the Medicaid program, State agencies provided most Medicaid coverage by paying health care providers on a fee-for-service (FFS) basis. Beginning in the 1980s and continuing throughout the 1990s, State agencies have increasingly provided Medicaid coverage through managed care contracts, under which they pay a health maintenance organization (HMO) or other similar entity a fixed monthly capitation payment for each Medicaid beneficiary [1] enrolled with the entity.

As these managed care programs have grown in number and complexity, so has Federal oversight, particularly oversight of quality of care. Many studies conducted by health services researchers indicate that, with few exceptions, the quality of care furnished by managed care organizations [2] (MCO) is similar to that furnished by FFS providers. Despite these findings, the quality of managed care has received increased attention from the Congress, HCFA and the States. This has been—

- Prompted originally by the fact that, in the early years of Medicaid managed care, there were highly publicized accounts of Medicaid enrollees encountering barriers to accessing care, and other quality-related problems;
- Encouraged by developments in the private sector, such as the use of ''continuous quality improvement'' and ''value-based purchasing'', which can be applied in the public sector to obtain

[1] The term ''beneficiary'', used throughout the preamble is synonymous with the term ''recipient'', used in the text of the regulation. Both refer to an individual who is eligible for and receiving Medicaid benefits.

[2] Section 4701(b) of the Balanced Budget Act of 1997 (BBA) established this term to encompass not only HMOs but also M+C organizations, other types of organizations that may participate in the Medicare program, and other public or private organizations that meet specified statutory requirements.

high quality health care for Medicaid beneficiaries; and

• Made feasible by the fact that an MCO that contracts to furnish defined services to a defined population can be held accountable in a way that is not possible under FFS Medicaid. For example, under FFS Medicaid, if a child does not receive an immunization, it is difficult to place responsibility on any of the providers that may have treated that child for different illnesses.

As a result of the above, the number of legislative, regulatory, and HCFA initiatives to improve health care quality have increased both in number and in sophistication.

Federal statutes governing Medicaid managed care contracts did not contain provisions explicitly addressing quality of care until 1986. However, before that date, our regulations required HMOs to have an internal quality assurance system and required State agencies to conduct periodic medical audits to ensure the furnishing of quality health care and access to that care. In the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), the Congress called for a new approach that complemented an HMO's internal quality assurance program and the periodic medical audits conducted by State agencies. OBRA '86 required that each State agency that contracted with an HMO use an independent external organization to conduct an annual review of the quality of services furnished to Medicaid beneficiaries served by each HMO.

Between 1986 and 1997, we and the State agencies developed tools to use in implementing these quality oversight responsibilities. In 1991, we began the Quality Assurance Reform Initiative (QARI), which in 1993, resulted in the publication of, ''A Health Care Quality Improvement System for Medicaid Managed Care-A Guide for States.'' This document contained: (1) A framework for quality improvement systems for Medicaid managed care programs; (2) guidelines for internal quality assurance programs of Medicaid HMOs and similar organizations; (3) guidelines for clinical and health services focus areas and use of quality indicators and clinical practice guidelines; and (4) guidelines for the conduct of external quality reviews (EQRs) mandated in OBRA '86.

In 1995, HCFA in collaboration with the National Committee for Quality Assurance (NCQA) and the American Public Human Services Association (APHSA), produced a Medicaid version of the Health Plan Employer Data and Information Set (HEDIS), a standardized quality performance measurement system used by private sector purchasers of managed care. We also contracted with NCQA to produce, ''Health Care Quality Improvement Studies in Managed Care Settings—Design and Assessment: A Guide for State Medicaid Agencies''.

## II. The Balanced Budget Act of 1997

The Balanced Budget Act of 1997 (BBA) added to the Act a new section 1932 that pertains to Medicaid managed care. Most of the provisions of section 1932 would be implemented in accordance with a proposed rule that was published in September, 1998 and is discussed under part III C of this preamble.

Section 1932(c), added by section 4705 of the BBA, describes in detail how quality measurement and performance improvement methods should be applied to Medicaid managed care programs through two specific approaches:

• All State agencies must develop and implement a quality assessment and improvement strategy that includes: (1) standards for access to care; (2) examination of other aspects of care and services related to improving quality; and (3) monitoring procedures for regular and periodic review of the strategy. (This requirement was addressed in the September proposal.)

• State agencies that contract with Medicaid MCOs must provide for an annual external, independent review of the access to, timeliness of, and quality outcomes of the services included in the contract between the State agency and the MCO. (This requirement is addressed in this proposed rule.)

Section 1932(c) of the Act also requires the Secretary—

• In consultation with the States, to establish a method for identifying entities qualified to conduct EQR (section 1932(c)(2)(A)(ii)); and

• In coordination with the National Governors' Association (NGA), to contract with an independent quality review organization to develop the protocols to be used in EQRs (section 1932(c)(2)(A)(iii)).

For the first requirement, we obtained the input of an expert panel convened by the National Academy for State Health Policy (NASHP).

To meet the second requirement, on July 7, 1998, we issued a Request for Proposal (RFP) for one or more contractors to develop a set of review protocols for external quality review organizations (EQROs) to use in the conduct of EQRs. Two State representatives selected by the NGA were members of the panel which reviewed responding proposals. As a result of this competitive procurement, a contract was awarded to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to develop protocols for the activities we believed were most frequently conducted by EQROs. Our belief was subsequently confirmed through surveys conducted by the Department's Office of the Inspector General (OIG) and the NASHP. The JCAHO has not completed development of the protocols for EQR. Although the text of the protocols themselves will not be included in regulations text, this proposed rule does identify the areas to be covered by them and what is to be included in such protocols.

The other section 1932 provisions that are pertinent to this proposal are provisions that—(1) Require that the results of EQRs be made available to participating health care providers, enrollees and potential enrollees (section 1932(c)(2)(A)(iv)), and (2) Provide that a State agency—

• May, at its option, take steps to ensure that an EQR does not duplicate a review conducted either by a private independent accrediting organization or as part of an external review conducted under the Medicare program (section 1932(c)(2)(B)); and

• May exempt an MCO from EQR under certain specified conditions (section 1932(c)(2)(C)).

Section 4705(b) of the BBA provides for increased FFP (75%) for the costs of conducting EQR under Section 1932(c)(2)(A), providing the EQRO meets the requirements set forth in regulations. Under the OBRA '86 provision, 75% FFP is available only if EQR is conducted by a utilization and quality control peer review organization (PRO) or an entity that meets the requirements to be a PRO but does not have a PRO contract with Medicare. Accreditation organizations may also be used to conduct EQR, but their review activities are matched at the 50 percent rate under the current OBRA '86 rules.

## III Development of the Proposed Rule

### *A. Major Purposes*

In developing this proposed rule, we had two major purposes: (1) To provide flexibility for State agencies; and (2) to reflect the well-accepted advances in the technology of quality measurement and improvement.

Flexibility is particularly important because the EQR requirement is not new. States have been monitoring quality under the OBRA '86 requirements for which final regulations were never published. Accordingly, this proposal would not require State

agencies to dismantle EQR mechanisms that they have used and found to be effective and efficient. The BBA language calling for State agencies to develop their own Quality Assessment and Improvement Strategies, supports our approach of recognizing the unique characteristics of States, their managed care programs and the sophistication of the managed care marketplace within each State.

In addition, the BBA provides greater flexibility in the types of entities that State agencies may use to conduct EQR. Consequently, this rule allows State agencies to coordinate EQRs with other similar quality reviews conducted for other purposes, thereby reducing the burden to State agencies and EQROs in complying with the requirement.

Despite the necessary flexibility, the BBA ensures comparability among State EQR results by requiring us to develop protocols to be used by all State agencies and EQROs in conducting the reviews.

Although the definition of EQR (shown under part IV of this preamble) makes clear that EQR must be conducted by an EQRO, it does not preclude State agencies from using other entities to conduct additional activities to monitor quality. For example, State agencies may themselves collect performance measures or encounter data, or monitor MCOs for compliance with structural and operational quality standards, or contract with an entity other than an EQRO to perform these projects. This approach allows State agencies considerable flexibility in the conduct of quality review activities and permits them to continue current practices at the 50% administrative match rate.

With respect to the second purpose, there is growing acceptance of the health care industry's ability to measure and improve health care quality, as documented in the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, and the development of stronger tools to accomplish this measurement (such as the Consumer Assessment of Health Plans Study (CAHPS)). In developing this rule, we have incorporated best practices in the assessment and improvement of health care quality.

*B. Information Used*

In order to develop this proposal we needed information on—

- How States have implemented EQR requirements under OBRA '86; and
- What qualifications to require for EQROs.

State Experience Under OBRA '86

Because a final regulation for the OBRA '86 requirement was never published, State agencies have considerable latitude in defining the activities conducted as part of EQR. We knew that State agencies were using the EQR requirement to implement different approaches to quality review. For example, some State agencies use EQR to monitor HMO compliance with QARI standards, while others use EQRs to conduct focused studies on defined clinical topics, such as immunizations, to determine HMO performance. We did not know how widely State practices varied.

In order to determine the extent and the success of each variation, we relied on information from two sources. The first was a study conducted by the Department's Office of Inspector General (OIG) entitled, ''Lessons Learned From Medicaid's Use of External Quality Review Organizations'' published in September, 1998. This study reviewed the practices of seven States (Arizona, California, Massachusetts, Minnesota, Missouri, Ohio and Washington) that had considerable experience with Medicaid managed care or in working with EQROs. The study documented that focused studies of quality of care, that is, review of medical records to obtain information on services delivered to a group of individuals with the same health care needs, was the most frequent activity performed by EQROs. In these States, focused studies accounted for nearly 80 percent of their budgets for EQRO. However, in the OIG study, States expressed an awareness of the limitations of the use of focused studies alone, stating that they fail to offer a broad assessment of the care delivered to all those enrolled in a State's Medicaid managed care program. As summarized by the study: ''At best they capture a slice of care delivered to one or two sub populations. Even if a Medicaid agency designed the perfect system to capture prenatal care visits or child immunizations, this is only a tiny fraction of care provided to the Medicaid population.'' For this reason, State agencies are beginning to use EQROs to undertake other approaches to quality review, including: (1) Validation of encounter data or aggregate MCO-level performance measures; (2) individual case review; (3) evaluation of quality studies conducted by MCOs; (4) conducting beneficiary surveys; and (5) provision of technical assistance.

The OIG study also documented that these seven States had typically used Medicare PROs to conduct the EQRO function. This was generally satisfactory to the States, especially because most States use EQR to conduct focused studies. However, some State agencies expressed reservations about using PROs for other EQR functions, such as processing and verifying encounter data or conducting consumer surveys. As a result, all of the State agencies in this study contracted with entities other than their EQRO contractors to perform additional quality review activities even though the FFP rate for these services was 50%, rather than 75%. These entities included: universities, consulting groups, claims or data management groups, and survey firms. In addition, four of the seven had additional arrangements with State agencies other than the Medicaid agency, including Departments of Health, Departments of Mental Health, or State data entities. The two overall conclusions expressed by the OIG, report were that Medicaid agencies find value in using a variety of quality oversight functions in EQR, and that they would prefer to use several different types of contractors.

To obtain additional information, we contracted with the NASHP to conduct a more comprehensive survey of all State agencies using EQROs. The NASHP survey reaffirmed the OIG survey finding that focused quality of care studies were the most common EQRO activity, with additional activities including: data validation, random medical record review, surveys, data audits and validation, and contract compliance reviews. The survey also affirmed the States' desire to contract with additional types of organizations for their EQRs, although three State agencies explicitly recommended that new entities not be permitted. Those State agencies wishing to contract with new entities identified State entities other than Medicaid such as public health or insurance departments, and other entities such as universities, consulting firms and research foundations, as desirable organizations.

EQRO Qualifications

OBRA '86 as amended by OBRA '87 specified the types of entities State agencies could contract with to conduct EQR. The BBA, instead of specifying types of entities, requires the Secretary to consult with States and establish a method for the identification of entities that are qualified to conduct EQR. To fulfill this requirement, we contracted with the NASHP to convene an expert panel comprised of a majority of State representatives but also including consumer advocates and other stakeholders, an MCO representative, a

quality improvement expert and members of our staff. The expert panel met for two days to discuss the following:

- What is the skill set required to conduct the EQR scope of work?
- What does it mean for an EQRO to be ''independent''?
- Who should be the authority to designate ''qualified'' entities to serve as EQROs?
- Should these designations be made on a categorical or case-by-case basis?
- Must all EQR activities be conducted by a single entity or may several entities conduct EQR activities, and may entities use subcontractors?

We used the recommendations included as part of the NASHP report of the meeting to develop the provisions of this proposed rule.

*C. Relation to Other Proposed Rules*

On September 29, 1998, at 63 FR 520220, we published a proposed rule identified as HCFA–2001–P, Medicaid Managed Care Provisions (September proposal). That rule proposed to add to the Medicaid regulations a new part 438 that includes a subpart E—Quality Assessment and Performance Improvement. Under subpart E, it is a State's responsibility to arrange for an annual external independent review of the timeliness, access, and quality of the services that each contracting MCO furnishes to its Medicaid enrollees. The September proposal did not include the specific EQR provisions because we had not yet complied with the BBA's requirement to consult with States to establish a method for identifying entities that are qualified to conduct EQR. Now that we have complied with this requirement, we can propose the rules for EQR.

The September proposal includes a § 438.8(h) which lists those requirements, set forth elsewhere in part 438, that also apply to Prepaid Health Plans (PHPs). Prepaid Health Plans, like MCOs, are organizations paid on a prepaid capitation basis for services furnished to enrollees, but unlike MCOs, they do not always provide comprehensive health care services nor do they always assume risk. (Examples of PHPs, are managed dental or behavioral health plans.)

When part 438 is published in final form (following consideration of comments received on both proposed rules), we plan to amend the § 438.8(h) list to include the EQR requirements as applicable to PHPs, for the benefit of PHP enrollees. As in the case of PHP requirements generally, this requirement would be promulgated under section 1902(a)(4) of the Act which authorizes the Secretary to establish requirements necessary ''for the proper and efficient operation of the plan.'' We also believe that this is consistent with Congressional intent. In the Joint Explanatory Statement of the Committee of the Conference accompanying the BBA, the section entitled ''Current Law,'' includes the following: ''States are required to obtain an independent assessment of the quality of services furnished by contracting HMOs and prepaid health plans (those offering a non-comprehensive set of services under partial capitation), using either a utilization and quality control peer review organization (PRO) under contract to the Secretary or another independent accrediting body.'' Although the OBRA '86 requirement did not apply to PHPs, the fact that the Congress believed that it did and chose not to exempt PHPs, as it did primary care case managers, we take as a sign that the Congress perceives EQR requirements as appropriately applied to PHPs.

Currently, 42 CFR 434.53 requires States to have a system of periodic medical audits to ensure that each HMO and PHP furnishes quality and accessible health care to enrollees. Our September proposal eliminates the periodic Medical Audit requirement. We intend this new EQR requirement to replace the requirement on PHPs for periodic medical audits.

Because PHPs do not always provide comprehensive services, we intend that an EQR of a PHP will assess only the scope of services for which the State has contracted. We invite comment on our decision to apply the EQR requirement to PHPs. We will only consider comments that pertain specifically to our proposal to include EQR requirements in § 438.8(h), and not on the broader issue of subjecting PHPs to other MCO quality requirements. Comments on those other requirements would have been appropriate in response to the September proposal.

In addition to proposing that these provisions apply to PHPs, we are also proposing to apply the EQR provisions to organizations that have comprehensive risk contracts but are exempt from 1903(m) requirements, such as Health Insuring Organizations (HIOs) which began operating prior to January 1, 1986, certain county-operated HIOs in California, and entities described in section 1903(m)(2)(B). As reflected in § 438.6 of the September 29, 1998 proposed rule, only contracts with HIOs that began operating on or after January 1, 1986 are subject to MCO requirements unless they have been specifically exempted by statute from these requirements, as in the case of certain county operated HIOs in California. As discussed above, pursuant to our authority under section 1902(a)(4) to establish requirements necessary for ''proper and efficient administration,'' we have proposed to apply several beneficiary protections and quality-related requirements (including the EQR requirement proposed in this rule) to PHPs, which do not have comprehensive risk contracts.

Entities with comprehensive risk contracts that have been exempted by statute from the MCO requirements in section 1903(m) and section 1932, however, were not included in our proposed revised definition of PHP. As discussed above, we did not believe it was appropriate to subject these entities, in effect, to virtually the full range of MCO requirements (as we proposed to do in the case of PHPs) when Congress had provided these entities with explicit statutory exemptions from these requirements. We do not believe, however, that these entities should be exempted entirely from any check on the quality of the services they provide to their enrollees. We accordingly are proposing in section § 438.1 (c) to require compliance with EQR requirements by entities with comprehensive risk contracts that are statutorily exempt from the requirements in section 1903(m)(2)(A). We believe this is consistent with Congressional intent to ensure quality outcomes and timeliness of and access to services of all Medicaid beneficiaries enrolled in capitated risk arrangements. We invite comment on our decision to apply the EQR requirement to entities with statutory exemptions from section 1903(m)(2)(A) requirements.

The final rule for part 438 will probably assign a separate subpart for the rules specific to EQR.

## IV. Provisions of the Proposed Rule

*A. Definitions (Section 438.2)*

Section 438.2 establishes ''EQR'' and ''EQRO'' as representing ''external quality review'' and ''external quality review organization'' respectively. It also defines four terms frequently used in the text:

''External quality review'' means the analysis and evaluation, by an EQRO, of aggregated information on timeliness, access, and quality of health care services furnished to Medicaid enrollees by each MCO, and other related activities performed by an EQRO.

''External quality review organization'' means an organization

that meets the competence and independence requirements set forth in § 438.354, and performs EQR.

''Quality'', as it pertains to EQR, means the degree to which an MCO maintains or improves the health outcomes of its enrollees through its structural and operational characteristics and through the provision of services. This definition recognizes structure, process, and outcomes as the variables that affect and constitute the delivery of appropriate health care and that have historically been used in the review of quality of care.

''Validation'' means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

*B. State Responsibilities (Section 438.350)*

Section 438.350 sets forth the State's responsibilities related to EQR. Each State agency that contracts with MCOs under section 1903(m) of the Act must ensure that—

- Except as provided in § 438.362, an annual EQR is performed by a qualified EQRO for each contracting MCO;
- The EQRO has sufficient information to use in performing the review;
- The information that the State agency provides to the EQRO is obtained through methods consistent with protocols specified by HCFA; and
- The results of the EQR are made available, upon request, to specified groups and to the general public.

The information that the State agency must make available to the EQRO is specified in § 438.358. The information that constitutes the ''results'' of the EQR is specified in § 438.364.

Section 1932(c)(2)(A) of the Act requires that each contract with an MCO ''provide for an annual (as appropriate) external independent review, conducted by a qualified independent entity* * *''. We have interpreted the parenthetical statement (for which there is no explanation in the legislative history) to be a reference to those MCOs that may be exempted from EQR under section 1932(c)(2)(C) of the Act on the basis of ''deemed compliance.'' We invite comment on other possible interpretations.

*C. External Quality Review Protocols (Section 438.352)*

In our RFP for the development of protocols, we defined them as ''detailed instructions to be followed by personnel performing reviews of health care quality.'' Protocols must specify: (1) The data to be gathered, that is, the substantive areas to be covered by the protocol; (2) the source of the data; (3) detailed procedures to be followed in collecting the data to promote its accuracy, validity, and reliability; (4) the proposed methods for valid analysis and interpretation of the data; and (5) all instructions, guidelines, worksheets and any other documents or tools necessary for implementing the protocol.

The protocols that the JCAHO is developing under the guidance of an expert panel are reflected in proposed section 438.358 discussed below. They will address: (1) Monitoring for compliance with structural and operational quality standards; (2) validating client-level data; (3) calculating performance measures; (4) validating performance measures produced by MCOs; (5) conducting quality-assessment and performance-improvement projects; (6) validating MCO-conducted quality-assessment and performance-improvement projects; (7) conducting studies on quality, focused on a particular aspect of clinical or non-clinical services furnished at a particular time; (8) validating consumer or provider surveys; and (9) administering consumer or provider surveys.

We have asked the JCAHO to draw from existing protocols that have been tested for reliability and validity and that have been used in the public and private sectors to conduct reviews of the quality of MCO services, consistent with current industry practice. We have also expressed a preference for protocols that are in the public domain.

We expect that the protocols will be detailed and many pages in length. This is one reason for not including them in our regulations. Another reason is the fact that quality measurement is a rapidly changing technology. Protocols developed in the private sector for validation of performance measures and administration of consumer surveys are revised at least annually. The delays inherent in revising regulations would make it difficult to make such frequent changes.

All activities that provide information for EQR must use protocols that are consistent with those that we specify. This will ensure that the conduct of the activities enhances the quality of EQR for State agencies and that the conduct of the activities is methodologically sound. However, by requiring protocols that are ''consistent'', rather than ''identical'', with those that we specify, we leave the State agencies free to improve their protocols continuously, as the art and science of quality measurement improve.

*D. Qualifications of External Quality Review Organizations (Section 438.354)*

Section 438.354 sets forth the requirements that an entity must meet in order to qualify as an EQRO. We worked in consultation with States, consumer advocates, and other stakeholders, under the auspices of NASHP, to determine how to ensure that EQROs are both ''competent'' and ''independent''.

This proposed rule does not define categories of entities that are qualified to perform EQR. Rather, it proposes that in order to qualify, entities must meet specified competence and independence standards. To meet the competence standards, the entity must have at least the following:

- Staff with knowledge of (1) Medicaid beneficiaries, policies, data systems, and processes; (2) managed care delivery systems, organizations, and financing; (3) quality assessment and improvement technologies; and (4) research design and methodology;
- Sufficient physical, technological, and financial resources to conduct EQR; and
- Other clinical and nonclinical skills to carry out the review and to supervise the work of any subcontractors.

To meet the independence requirement, we propose two tests:

- The EQRO and any subcontractors must be independent from the State Medicaid agency and from any MCO they review.
- The relationship between the MCO and the EQRO must be such as to preclude conflict of interest.

The first test would allow State entities to qualify as EQROs, with the following limitations:

A State entity could not qualify if it (1) Has Medicaid purchasing or managed care licensing authority; (2) delivers any health care services to Medicaid beneficiaries; or (3) conducts, on the State's behalf, any other ongoing Medicaid program operations related to oversight of the quality of MCO services. In addition, the State entity must be governed by a Board or similar body, the majority of whose members are not government employees.

We were concerned about the limitation on board membership. We wondered whether it was feasible to have a State entity with an oversight body composed predominantly of non-State employees. We found that a number of State entities do have such boards. For example, Vermont's Program for Quality in Health Care is an organization authorized by the Vermont

legislature to oversee the quality of care for both commercial and public consumers. It is a non-profit organization that is governed by a board of directors, the majority of whom, are not government employees and which includes representatives of consumers, hospitals, insurers, MCOs, employers, physicians, and State government. The organization is charged with improving the quality, efficiency, and cost effectiveness of Vermont's health care system. It measures health care quality through data collection and analysis, and works with health care providers and others to develop standards of care and indicators of quality.

Maryland's Health Care Access and Cost Commission (HCACC), created in 1993, is an independent commission with nine members who are appointed by the governor with the advice and consent of the Senate. The majority of the nine Board members are not government employees. Among its responsibilities, the HCACC is required to establish and implement a system to comparatively evaluate the quality and performance of MCOs.

The NASHP expert panel also recommended that EQROs be required to have participation by Medicaid beneficiaries. With respect to this recommendation, we welcome such participation, however, we do not propose to mandate it, for two reasons:

1. EQR is only one facet of the State's quality assessment and performance improvement strategy.

2. We believe that stakeholder input on EQR might be more effective if provided to the State agency (rather than the EQRO), as it develops that strategy.

The second test of independence from the MCO applies to all entities contracting under EQR. The NASHP summary report, based on its expert panel's input, recommended providing that an EQRO may not review an MCO if either has an ownership interest greater than 5 percent in the other, or if they share management or corporate board membership. That would be consistent with our disclosure of ownership and related information requirements under our program integrity regulations (part 420 for Medicare, and part 455 for Medicaid). However, we are proposing a broader approach that is consistent with other HCFA regulations on contracting and is based on the concept of ''affiliation'',[3] as the term is explained in 48 CFR 19.101.[4] In accordance with that regulation, an EQRO and an MCO would be considered to be ''affiliated'' if either one controls or has the power to control the other, or another entity controls or has the power to control both. We believe that this concept of ''control'' can better ensure that no actual conflicts of interest exist between the EQRO and the MCO it reviews. We request comments on how better to identify situations that create conflict of interest, on our proposing to allow State entities to qualify as EQROs, and on our decision to apply the ''independence '' requirement to subcontractors as well as contractors.

Another NASHP summary report recommendation based on its expert panel's input was that EQROs be selected by State agencies through RFPs that would not require prior approval by us, but would be subject to review later to ensure that, as a condition for FFP at the 75 percent rate, the State agency followed all applicable procedures and criteria. We note that this recommendation requires no changes or additions to current law because it is current practice for State agencies to use RFPs to select EQROs. It is also standard practice for our regional office staff to monitor implementation of Medicaid managed care initiatives. With respect to EQR, Regional Office staff may review the State's most recent RFP for external review services, the EQR contract, or the EQR reports.

*E. State Contract Options (Section 438.356)*

Section 438.356 sets forth requirements that State agencies must follow, and options that they may use in selecting EQROs. On the basis of the NASHP expert panel's recommendations, as well as the findings of the OIG report, we propose that State agencies may contract with more than one EQRO and each EQRO may use subcontractors. EQROs that use subcontractors are accountable for and required to oversee all EQR activities performed by the subcontractors. In addition, each contractor must meet the competency requirements and each contractor and subcontractor must meet the independence requirement.

We considered requiring only the contractor to meet the test of independence. We determined that such an approach would permit entities with conflicts of interest to serve as subcontractors under a ''shell'' contractor, and thus not ensure a truly independent review.

This section also requires that State agencies follow an open competitive procurement process that is in accordance with State law and regulation and consistent with 45 CFR part 74, as it applies to State procurement of Medicaid services.

*F. Activities Related to External Quality Review (Section 438.358)*

Section 438.358 requires that the EQR use information obtained from specified mandatory activities that must be performed by the State agency or the EQRO; and identifies other optional activities that the State agency may wish to perform, or have the EQRO perform, to produce additional information for use in the EQR. The mandatory activities are consistent with the requirements set forth in the September proposal. The optional activities were not included in that proposal. They are, however, activities that both the OIG and the NASHP surveys identified as activities that States have found useful in reviewing quality. Inclusion of these optional activities would permit States to use their EQROs for the full range of activities they are now conducting. This section also authorizes States to use EQROs to provide technical assistance to MCOs.

This rule proposes that each year, information to be used by the EQRO be obtained from the validation of performance improvement projects performed that year and the validation of performance measures reported that year. However, we recognize that a State, or Medicare, or a private accreditation organization may review MCO compliance with structural and operational quality standards less frequently than once a year. For example, NCQA and JCAHO generally perform their accreditation reviews once every three years. Because of this, we propose that the information used by the EQRO on this type of review must be from the most recent review performed within the previous three years.

*G. Non-Duplication of Mandatory Activities (Section 438.360)*

Section 438.360 is based on section 1932(c)(2)(B) of the Act which provides the option for a State agency to exempt an MCO from specified EQR-related activities that would duplicate activities conducted as part of Medicare reviews or independent accreditation surveys.

[3] That is the concept we propose to use in implementing the Medicare Integrity Program (MIP) established by the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191). The MIP proposed rule published in March 1998, identifies offerors or entities as having a conflict of interest if they are ''affiliated.''

[4] Title 48 of the CFR contains the Federal Acquisition Regulations (FAR) system, which ''is established for the codification and publication of uniform policies and procedures for acquisition by all executive agencies.'' Most government acquisition is accomplished through contracting.

For this provision, we had to determine how a State agency could obtain information about the quality of care found through Medicare reviews or accreditation if there was no EQR to provide information. Moreover, because Medicare serves the elderly and disabled, while Medicaid predominantly serves families and children, we needed to take into account that review activities usually differ for these populations in terms of the types of data collected, the measures used, and the studies conducted. These differences limit the extent to which they can be considered to duplicate each other. Accordingly, we propose that an MCO that is a certified M+C organization with a current Medicare contract—

- Qualifies for exemption if it has had an independent quality review under Medicare or is fully accredited by a private accreditation organization; but
- The exemption applies only to the activities specified in § 438.358(a)(2). Those are specific to reviewing compliance with standards for (1) availability of services; (2) continuity and coordination of care; (3) coverage and authorization of services; (4) establishment of provider networks; (5) enrollee information; (6) enrollee rights; (7) confidentiality; (8) enrollment and disenrollment; (9) grievance systems; (10) subcontractual relationships and delegation; (11) use of practice guidelines; (12) health information systems; and (13) mechanisms to detect both underutilization and overutilization of services as part of the quality assessment and performance improvement programs.

We believe that these activities are essentially the same regardless of the population served, but the activities specified in § 438.358(a)(1) are sensitive to the type of population served. For example, performance improvement projects that target the elderly would not be appropriate for addressing maternal and child health issues, and would not be considered duplicative. The rule provides one exception to this limitation: a State agency may exempt from all mandatory activities (listed in paragraphs (a)(1) and (a)(2) of proposed § 438.358) any MCO that serves only individuals who are eligible for both Medicare and Medicaid. In that situation, there is no reason for concern, since the population served is the same for both programs.

The State agency must require each MCO exempted under this section to make available to the State agency all reports and findings and the results of the Medicare quality review or the accreditation survey, in order to: (1) Provide that information to the EQRO; and (2) ensure that State agencies and Medicaid beneficiaries have access to comparative information on MCOs and M+C organizations.

*H. Exemption From External Quality Review (Section 438.362)*

This section implements section 1932(c)(2)(C) of the Act which provides that a State agency may exempt an MCO from the EQR requirements in section 1932(c)(2)(A) if the MCO has a current Medicare contract under Part C of title XVIII or under section 1876 of the Act; and, for at least two years, has had in effect a Medicaid contract under section 1903(m) of the Act.

In developing this proposed rule, we asked ourselves (1) how to interpret the statutory requirements for having a Medicare contract, and having had a Medicaid contract for at least two years; (2) whether the exemption should apply to an MCO whose Medicare and Medicaid contracts do not cover the same geographic area; (3) whether the Congress intended that the State agency grant an exemption without consideration of the MCO's performance during the preceding 2-year period; and (4) what information, if any, the State agency needs to obtain with respect to an exempted MCO. On the basis of our responses to those questions, we added three requirements. We particularly request comments on these requirements because they are not based on any explicit language in the statute or the Conference Committee Report.

The first requirement is that the two contracts cover all or part of the same geographic area. The purpose is to prevent exemption on the basis of a Medicare contract that covers a geographic area, for example, another State or a different part of the same State, that is completely different from the area covered by the MCO's Medicaid contract. (§ 438.362(a)(2))

We believe that an MCO that serves different areas typically has different provider networks in each area. Since research has clearly shown variations in practice patterns among physicians in different geographic areas, it is reasonable to interpret the deemed compliance provisions as requiring some common service areas.

The second added requirement is that, during each of the two years preceding the granting of an exemption, the MCO has had an EQR that found it to be performing acceptably with respect to the timeliness, access, and quality of health care services provided to Medicaid enrollees. (§ 438.362(a)(3)).

We considered several possible rationales for the statutory provision that grants exemption on the basis of two-year participation in the Medicaid program:

- After two years of dealing with the MCO as a contractor, the State agency is sufficiently familiar with its performance generally, thus making EQR unnecessary.
- Two years of serving the Medicaid population (a different population than Medicare's) is sufficient to exempt the MCO from EQR.
- During each of the two years of the Medicaid contract, the MCO will have been subject to the section 1932(c)(2)(A) requirements, and will have been able to demonstrate its performance through the annual EQR, demonstrating that the MCO's ongoing Medicare compliance is likely to remain predictive of high quality Medicaid services.

Given the importance that the Congress has placed on quality in the BBA provisions, we are proposing to interpret the two year rule to have been adopted based upon the third rationale above. Accordingly, we propose that the State agency have the option to exempt the MCO if, during the two preceding years of Medicaid contract under section 1903(m) it has been subject to EQR and been found to be performing acceptably with respect to the timeliness, access, and quality of care furnished to Medicaid enrollees. The State agency could not exempt an MCO that, during the previous two-year period had been found to have significant problems requiring corrective action. We note that our interpretation would effectively delay exercise of the option until at least two years after this rule is published in final.

The third added provision is that the State agency require each exempted MCO to provide it, annually, with copies of all Medicare reviews performed by us, or by any of our agents or any private accreditation organization, with respect to the timeliness, access, or quality of its services. (§ 438.362(b)) The rationale for this requirement is that the statutory provision exempts the MCO from EQR requirements specifically, but not from continued State agency oversight of the quality of MCO services.

*I. EQR Results. (Section 438.364)*

Section 438.364 requires that the EQR produce the following information:

- A detailed technical report that describes the following for each activity conducted under accordance with § 438.358: (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 in accordance with § 438.358 were aggregated, analyzed, and the conclusions were drawn as to the quality of the care furnished by the MCO.

• A detailed assessment of each MCO'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.

• Comparative data about all MCOs, as determined appropriate by the State agency.

• An assessment of the degree to which each MCO addressed effectively the recommendations for quality improvement, as made by the EQRO during the previous year's EQR.

We considered three alternatives for the level of detail of the information to be released to the public as EQR ''results.''

1. Do not provide a Federal definition of what constitutes ''results'' but allow each State agency to develop its own definition. This option would provide the greatest flexibility but was not selected because we believe that the statute intended a Federal ''definition'' to ensure that all State agencies provide sufficient information.

2. Require that all validated data and information be made available. Although this option would provide consumers with great detail about every aspect of MCO performance, the information would lack the sense of context necessary to ensure appropriate interpretation. It would impose additional burdens on State agencies for the release of large quantities of data, and would also be inconsistent with what experts have advised us is the best way to share information with consumers for their decision making, for example, to help potential enrollees choose among available MCOs.

3. Require that State agencies provide copies only of the summary findings, conclusions, and recommendations of the EQR. This would include the highest level conclusions drawn from a synthesis of all available information on MCO performance.

This proposed rule requires State agencies to provide information sufficient to enable interested parties to evaluate the conclusions of the EQR. To promote confidence in the validity of the conclusions, States may wish to release, in addition to the technical report, the more detailed underlying data to researchers or others as the States deem appropriate. However, the proposed rule does not require the States to do so. In addition, these data may be available through State-based authorities similar to Freedom of Information Act requirements for individuals to request and receive as much of the detailed information that goes into an EQR analysis and report as they want. (§ 438.364(a))

This section also (1) gives examples of groups of interested parties to which State agencies would provide copies, of the EQR results, upon request; (2) specifies that they must also give them to members of the general public who request them (§ 438.364(b)); and (3) provides that the information released may not disclose the identity of any patient (§ 438.364(c)).

*J. Federal Financial Participation (FFP) (Section 438.370)*

Section 438.370 provides that FFP at the 75 percent rate is available in expenditures for EQR, including the production of EQR information, performed by EQROs and at the 50 percent rate in expenditures for EQR-related activities performed by any entity that does not qualify as an EQRO. The 50 percent rate applies even if the activities are of the same type as those performed by EQROs.

## V. Effective Date of the Final Rule

When this regulation is published as a final rule, we intend to make it effective 60 days following publication. Provisions that must be implemented through contracts with EQROs will be effective with contracts entered into or revised on or after 60 days following the effective data, but no longer than 12 months from the effective date.

## VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement report is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA, requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for §§ 438.360, 438.362 and 438.364 of this document that contain information collection requirements.

*Section 438.360 Nonduplication of Mandatory Activities*

In order to avoid duplication, the State agency may exempt an MCO from mandatory activities (as specified in § 438.358) if the conditions of paragraph (b) or paragraph (c) of this section are met. To demonstrate compliance with these requirements an MCO must provide to the State agency, all the reports, findings, and other results of the Medicare review or the private accreditation survey.

The burden associated with these requirements is the time and effort for an MCO to disclose all the reports, findings, and other results of the Medicare review or the private accreditation survey to the State agency. Our current data indicate that there are approximately 420 MCOs and 90 PHPs providing Medicaid services. Of these, approximately 135 are Medicaid only MCOs. We believe that there is the potential for States to allow the remaining 285 MCOs 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 4 hours to disclose the necessary documentation to the State. Therefore, the total burden associated with this requirement is 285 MCO's × 4 hours = 1140 annual burden hours.

This section also requires that a State agency provide all the reports, findings, and other results of the Medicare review or the private accreditation survey to the appropriate EQRO. We estimate that it will take, on average, 4 hours for a State to disclose the necessary documentation to the appropriate EQRO. The total annual burden associated with this requirement is 1140 hours.

*Section 438.362 Exemption From External Quality Review*

Each year, exempted MCO's must provide to the State agency the most recent Medicare review findings reported to the MCO by HCFA or its agent. This information must include (1) all data, correspondence, information, and findings pertaining to the MCO's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities; (2) all measures of the MCO's

performance; and (3) the findings and results of all performance improvement projects pertaining to Medicare enrollees.

If an exempted MCO 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 Subpart D of part 422 of this chapter or to deem compliance with Medicare requirements as provided in § 422.156, the MCO 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.

The burden associated with these requirements is not applicable for two years following the final publication of this regulation. After two years, the time and effort for an exempted MCO to disclose the findings of its most recent Medicare review or private accreditation survey to the State agency will be the burden associated with these requirements. We believe, of the approximately 285 MCOs that potentially may provide Medicare services in addition to Medicaid services, State agencies will allow for approximately 10% 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 285 MCO's × 8 hours = 228 annual burden hours.

*Section 438.364 External Quality Review Results*

Each EQRO is required to submit to the State agency a detailed technical report that describes, for each EQR and each related mandatory and optional activity undertaken by the EQRO, 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. In addition, the report must include: (1) A detailed assessment of each MCO'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; (3) as the State agency determines methodologically appropriate, comparative information about all MCOs, and (4) an assessment of the degree to which each MCO 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 a EQRO to submit to a State agency a detailed technical report for each EQR conducted. It is estimated that it will take an EQRO 160 hours to prepare and submit the necessary documentation to the State agency. Therefore, the total burden associated with this requirement is, 510 technical reports (420 MCOs + 90 PHPs) × 160 hours = 81600 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, 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 4 hours to disclose the required information. Therefore, the total burden associated with this requirement is 420 MCOs + 90 PHPs × 25 requests per MCO or PHP × 4 hours = 51000 annual burden hours.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. We will also submit the final EQR protocols upon their completion to OMB. These requirements are not effective until they have been approved by OMB. As stated in the preamble of this rule, the EQR protocols are detailed instructions to be followed by personnel performing reviews of health care quality. The JCAHO is developing these protocols under the guidance of an expert panel. All activities that provide information for EQR must use protocols that are consistent with the protocols being developed. This will ensure that the conduct of the activities enhances the quality of EQR for State agencies and that the conduct of the activities is methodologically sound.

We anticipate that the protocols will be complete in the spring of 2000. Upon their completion, a **Federal Register** notice will be published. To obtain a copy of the protocols when they become available, access them on the HCFA Internet homepage at www.hcfa.gov, or submit a request to the HCFA address below: Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; Attention Julie Brown, HCFA–2015–P.

If you comment on any of these information collection and record keeping requirements, please mail 3 copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; Attention Julie Brown, HCFA–2015–P and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Lori Schack, HCFA Desk Officer.

## VII. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

## VIII. Impact Statement

*A. Regulatory Impact Analysis*

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, non-profit organizations and governmental agencies. Most hospitals and other providers and suppliers are

small entities, either by nonprofit status or by having revenues of $5 million or less annually. Individuals and States are not included in the definition of a small entity.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

The Unfunded Mandates Reform Act (Public Law 104–4) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $100,000,000 or more.

The rule implements Medicaid provisions as directed by the BBA; thus, alternatives were not considered. The only alternative would be to seek repeal of the legislation. This would be inconsistent with the major focus of the new provisions: protection of beneficiary rights in a health care system in which MCOs have gained broad powers.

We do not anticipate that the provisions in this proposed rule will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on State agencies and MCOs, but not directly on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs. Furthermore, the impact will also vary according to each hospital's current procedures and level of compliance with existing law and regulation pertaining to Medicaid managed care. For these reasons, this proposed rule would not have a significant impact on the operations of a substantial number of hospitals. The only other small entity affected by these regulations would be the EQROs. However, this rule does not impose additional burdens on them. Instead, the rule offers these organizations the benefit of opportunities for additional revenues. Thus we certify that this rule will not have a significant economic impact on a substantial number of small entities.

We do not anticipate a significant increase in Medicaid expenditures as a result of the publication of these regulations for the following reasons. First, 44 States, accounting for nearly 98 percent of Medicaid administrative expenditures, are currently obtaining 75 percent enhanced FFP for EQR activities carried out by PRO and PRO-like organizations. Permitting these State agencies to claim 75 percent matching for EQR activities conducted by the additional types of entities allowed by these regulations would therefore not result in increased costs to the extent that State agencies switch from PRO or PRO-like organizations to these additional entities. Moreover, we believe that, by expanding the pool of organizations available to conduct EQR, these State agencies may be able to negotiate savings compared to current costs of dealing with PRO and PRO-like organizations. Additional savings may be realized through opportunities afforded by the proposed rule to coordinate EQR activities with quality reviews conducted for other purposes, as discussed above. Additional costs may arise where State agencies currently conduct quality review activities at 50 percent Federal matching rate that would now qualify for 75 percent, and from new EQR activities undertaken as a result of the BBA requirements.

In addition, even though we are proposing to extend this requirement to PHPs, again we do not expect this to significantly increase Medicaid expenditures. PHP costs account for approximately 5 percent of the payments we make to capitated arrangements. Furthermore, State agencies currently conduct quality review activities on PHPs at a 50 percent Federal matching rate. Additional costs may arise for States quality review activities that would now qualify for 75 percent and for new quality review activities undertaken as a results of the activities required in this proposed rule.

Although we cannot quantify these various cost and savings effects, we believe that their net impact would be well below the $100 million annual threshold for a major rule, and therefore that a regulatory impact analysis is not required. The impact of this proposed regulation is subsumed in estimates of the aggregate impact of the BBA, which have already been included in Medicaid baseline projections for the President's budget.

*B. Federalism*

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this proposed regulation will not significantly affect States rights, roles, and responsibilities. Section 1903(a)(30)(C) of the Act currently requires an EQR for each contract a State has with a section 1903(m) organization. In accordance with section 4705 of the BBA, this proposed rule would establish requirements and procedures for EQR of Medicaid MCOs. We propose to require States to ensure that an annual EQR is performed by a qualified EQRO for each contracting MCO, the EQRO has adequate information to carry out the review, and that the results of the reviews are made available to interested parties such as participating health care providers, enrollees, advocate groups, and the general public. We propose that these EQR requirements apply to PHPs and certain entities with comprehensive risk contracts that have been exempted from section 1903(m)(2)(A) requirements. We believe this is consistent with the intent of the Congress in enacting the quality provisions of the BBA. This proposed rule would not require State agencies to dismantle EQR mechanisms that they have used to meet section 1902 (a)(30)(C) of the Act and which they have found to be effective and efficient. Rather, this proposed rule would provide States greater flexibility in the types of entities they may use to conduct EQR.

We worked closely with States in developing this regulation. Specifically, in accordance with section 1932(c)(2)(A)(ii) of the Act, which requires the Secretary to consult with States to establish a method for identifying entities qualified to conduct EQR, we met with States and other stakeholders under the auspices of the National Academy of State Health Policy to establish a criteria to identify qualified entities. Most of the recommendations made at this meeting have been incorporated into this proposed rule. For recommendations not accepted, an explanation has been provided.

In addition, section 1932(c)(2)(A)(iii) requires the Secretary to coordinate with the NGA in contracting with an independent quality review organization to develop protocols to be used in EQR. To meet this requirement, we issued a RFP for one or more contractors to develop a set of review protocols for EQROs to use in the conduct of EQRs. Two State

representatives selected by the NGA were members of the panel that reviewed and rated responding proposals. Moreover, part of the development of the EQR protocols includes convening an expert panel for review and comment of the protocols. State representatives are included in this process.

**List of Subjects**

*42 CFR Part 433*

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and record keeping requirements.

*42 CFR Part 438*

Grant Programs—health, Managed care entities, Medicaid, Quality assurance, Reporting and record keeping requirements.

42 CFR Chapter IV would be amended as set forth below.

## A. PART 433—STATE FISCAL ADMINISTRATION

1. The authority citation for part 433 is revised to read as follows:

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

### § 433.15 [Amended]

2. In § 433.15, the following change is made: A new paragraph (b)(10) is added to read as set forth below.

### § 433.15 Rates of FFP for administration.

* * * * *

(b) * * *

(10) Funds expended for the performance of external quality review or the related activities described in § 438.358 of this chapter when they are performed by an external quality review organization as defined in § 438.2 of this chapter: 75 percent.

B. A new part 438 is added, to read as set forth below.

## PART 438—MANAGED CARE PROVISIONS

### Subpart A—General Provisions

Sec.

438.1 Basis, scope and applicability.
438.2 Definitions.

### Subparts B through D [Reserved]

### Subpart E—External Quality Review

Sec.

438.350 State responsibilities.
438.352 EQR protocols.
438.354 Qualifications of EQROs.
438.356 State contract options.
438.358 Activities related to external quality review.
438.360 Non-duplication of mandatory activities.
438.362 Exemption from external quality review.
438.364 External quality review results.
438.370 Federal financial participation.

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

### Subpart A—General Provisions

#### § 438.1 Basis, scope and applicability.

(a) *Statutory basis.* This part is based on section 1932(c)(2) of the Act.

(b) *Scope.* This part sets forth requirements for annual external quality reviews of each contracting MCO, including—

(1) Criteria that States must use in selecting entities to perform the reviews;

(2) Specifications for the activities related to external quality review;

(3) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation surveys; and

(4) Standards for making available the results of the reviews.

(c) *Applicability.* The provisions of this part apply to managed care organizations (MCOs), prepaid health plans (PHPs), and entities with comprehensive risk contracts that have been exempted by statute from the requirements in section 1903(m)(2)(A).

#### § 438.2 Definitions.

As used in this subpart—

*EQR* stands for external quality review;

*EQRO* stands for external quality review organization.

*External quality review* means the analysis and evaluation, by an EQRO, of aggregated information on timeliness, access, and quality of the health care services furnished to Medicaid recipients by each MCO and other related activities performed by an EQRO.

*External quality review organization* means an organization that meets the competence and independence requirements set forth in § 438.354, and performs external quality review.

*Quality,* as it pertains to external quality review, means the degree to which an MCO maintains or improves the health outcomes of its enrollees through its structural and operational characteristics and through the provision of services.

*Validation* means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

### Subparts B through D—[Reserved]

### Subpart E—External Quality Review

#### § 438.350 State responsibilities.

Each State that contracts with MCOs must ensure that—

(a) Except as provided in § 438.362, an annual EQR is performed by a qualified EQRO for each contracting MCO;

(b) The EQRO has information, obtained from the related activities described in § 438.358, to carry out the review;

(c) The information provided to the EQRO in accordance with paragraph (b) of this section is obtained through methods consistent with the protocols established under § 438.352; and

(d) The results of the reviews are made available as specified in § 438.364.

#### § 438.352 EQR protocols.

Each protocol must specify—

(a) The data to be gathered;

(b) The sources of the data;

(c) The detailed procedures to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) All instructions, guidelines, worksheets, and any other documents or tools necessary for implementing the protocol.

#### § 438.354 Qualifications of EQROs.

(a) *General rule.* The State must ensure that each organization it selects to perform EQR meets the requirements of this section.

(b) *Competence.* The organization must have at least the following:

(1) Staff with knowledge of—

(i) Medicaid recipients, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement technologies; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR.

(3) Other clinical and nonclinical skills to carry out the review and to supervise the work of any subcontractors.

(c) *Independence.* The organization and its subcontractors are independent from the State Medicaid agency and from the MCOs they review. In order to qualify as ''independent'' and serve as an EQRO—

(1) A State agency, department, university, or other State entity may not—

(i) Have Medicaid purchasing or managed care licensing authority;

(ii) Deliver any health care services to Medicaid recipients; or

(iii) Conduct, on the State's behalf, any other ongoing Medicaid program operations related to oversight of the quality of MCO services.

(2) A State agency, department, university, or other State entity must be governed by a Board or similar body the majority of whose members are not government employees.

(3) An EQRO may not review a particular MCO if either the EQRO or the MCO exerts control over the other. (As used in this paragraph, ''control'' has the meaning given the term in 48 CFR 19.101.)

**§ 438.356 State contract options.**

(a) The State must contract with one or more EQROs.

(b) Each contractor must meet the competence requirements as specified in § 438.354(b).

(c) Each contracting EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each contractor and subcontractor must meet the requirements for independence, as specified in § 438.354(c)

(e) For each contract, the State must follow an open, competitive procurement process that is in accordance with State law and regulations and consistent with 45 CFR part 74 as it applies to State procurement of Medicaid services.

**§ 438.358 Activities related to external quality review.**

(a) *Mandatory activities.* The EQR must use information obtained from the following activities which must be performed by the State or its agent or, if they are not so performed, must be performed by the EQRO:

(1) Each year, for each MCO, the EQR must use information obtained from the following:

(i) Validation of performance improvement projects that were required by the State and were performed during the preceding 12 months.

(ii) Validation of performance measures that the State required and that the MCO reported during the preceding 12 months.

(2) Each year, the EQR must also use information obtained from a review, conducted within the previous 3 year period, to determine the MCO's compliance with standards established by the State for the following:

(i) Availability of services.

(ii) Continuity and coordination of care.

(iii) Coverage and authorization of services.

(iv) Establishment of provider networks.

(v) Enrollee information.

(vi) Enrollee rights.

(vii) Confidentiality.

(viii) Enrollment and disenrollment.

(ix) Grievance systems.

(x) Subcontractual relationships and delegation.

(xi) Use of practice guidelines.

(xii) Health information systems.

(xiii) Mechanisms to detect both underutilization and overutilization of services as part of the quality assessment and performance improvement programs.

(b) *Optional activities.* The review may also use information derived from the following optional activities performed by the State or its agent, or the EQRO:

(1) The validation of client level data (such as claims and encounters) reported by the MCO.

(2) The administration or validation of consumer or provider surveys of quality of care.

(3) The calculation of performance measures in addition to those reported by the MCO and validated by the EQRO.

(4) The conduct of performance improvement projects in addition to those conducted by the MCO and validated by the EQRO.

(5) The conduct of studies on quality, focused on a particular aspect of clinical or non-clinics services at a point in time.

(c) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs to assist them in conducting activities related to the mandatory and optional activities that provide information for the EQR.

**§ 438.360 Nonduplication of mandatory activities.**

(a) *General rule* In order to avoid duplication, the State may exempt an MCO from mandatory activities (as specified in § 438.358) if the conditions of paragraph (b) or paragraph (c) of this section are met.

(b) *Certified M+C organization.* The State may exempt an MCO from the mandatory activity specified in § 438.358(a)(2), if the following conditions are met:

(1) The MCO is also a certified M+C organization with a current Medicare contract.

(2) The MCO meets either of the following conditions:

(i) The MCO's current structure and its compliance with the standards established by the State under § 438.358(a)(2) have been evaluated and approved by HCFA or its contractor.

(ii) The MCO is currently fully accredited by a private accrediting organization that HCFA approves and recognizes as having standards and review procedures at least as stringent as those established by HCFA for the mandatory activity specified in § 438.358(a)(2).

(3) The MCO provides to the State all the reports, findings, and other results of the Medicare review or the private accreditation survey. The State provides the information to the EQRO.

(c) *MCO serves only the dually eligible.* The State may exempt an MCO from the mandatory activities specified in § 438.358(a)(1) and (a)(2) if the following conditions are met:

(1) The MCO serves only individuals who receive both Medicare and Medicaid benefits.

(2) The Medicare review activities are substantially comparable to the State-specified mandatory activities in § 438.358(a)(1) and (a)(2).

(3) The MCO provides to the State all the reports, findings, and other results of the Medicare review. The State provides the information to the EQRO.

**§ 438.362 Exemption from external quality review.**

(a) *Basis for exemption.* The State may exempt an MCO from EQR if the following conditions are met:

(1) The MCO has a current Medicare contract under part C of title XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act.

(2) The two contracts cover all or part of the same geographic area.

(3) The Medicaid contract has been in effect for at least two consecutive years before the effective date of the exemption and during those two years the MCO has been subject to EQR under this part, and found to be performing acceptably with respect to the timeliness, access, and quality of health care services it provides to Medicaid recipients.

(b) *Information on exempted MCOs.* (1) *Information on Medicare review findings.* Each year, the State must obtain from each MCO that it exempts from EQR, the most recent Medicare review findings reported to the MCO by HCFA or its agent including—

(i) All data, correspondence, information, and findings pertaining to the MCO's compliance with Medicare

standards for access, quality assessment and performance improvement, health services, or delegation of these activities;

(ii) All measures of the MCO's performance; and

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Information on accreditation surveys.* (i) If an exempted MCO has been reviewed by a private accreditation organization, the State must require the MCO to ensure that the State receives a copy of all findings pertaining to its most recent survey if the accreditation survey has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter,

(B) To deem compliance with Medicare requirements, as provided in § 422.156.

(ii) These findings must include, but need not be limited to, accreditation survey results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

**§ 438.364 External quality review results.**

(a) *Information that must be produced.* The State must ensure that the EQR produces at least the following information:

(1) A detailed technical report that describes the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated, analyzed, and the conclusions were drawn as to the quality of the care furnished by the MCO. The report must also include the following for each activity conducted in accordance with § 438.358:

(i) Objectives;

(ii) Technical methods of data collection and analysis;

(iii) Data obtained; and

(iv) Conclusions drawn from the data.

(2) A detailed assessment of each MCO's strengths and weaknesses with respect to the timeliness, access, and quality of health care services furnished to Medicaid recipients.

(3) Recommendations for improving the quality of health care services furnished by each MCO.

(4) As the State determines methodologically appropriate, comparative information about all MCOs.

(5) An assessment of the degree to which each MCO has addressed effectively the recommendations for quality improvement, as made by the EQRO during the previous year's EQR.

(b) *Availability of information.* The State must provide copies of the information specified in paragraph (a) of this section, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, recipient advocate groups, and members of the general public.

(c) *Safeguarding patient identity.* The information released under paragraph (b) of this section may not disclose the identity of any patient.

**§ 438.370 Federal financial participation.**

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR information), performed by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities performed by any entity that does not qualify as an EQRO.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance)

Dated: August 2, 1999.

**Michael M. Hash,**

*Deputy Administrator, Health Care Financing Administration.*

Approved: September 9, 1999.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 99–31101 Filed 11–30–99; 8:45 am]

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## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

## 45 CFR Parts 2522 and 2525

**RIN 3045–AA09**

## AmeriCorps Education Awards

**AGENCY:** Corporation for National and Community Service.

**ACTION:** Proposed rule.

**SUMMARY:** We propose to amend several provisions relating to the AmeriCorps education award, including those governing the circumstances under which an AmeriCorps member may be determined eligible for a pro-rated education award and the ways in which participants may use the award.

**DATES:** The deadline for written comments is January 31, 2000.

**ADDRESSES:** Comments may be mailed or delivered to Gary Kowalczyk, Coordinator of National Service Programs, Corporation for National and Community Service, 1201 New York Avenue NW, Washington, D.C. 20525, sent by facsimile transmission to (202) 565–2784, or sent electronically to gkowalcz@cns.gov. Copies of all communications received will be available for review at the Corporation by members of the public.

**FOR FURTHER INFORMATION CONTACT:** Gary Kowalczyk, Coordinator of National Service Programs, Corporation for National and Community Service, (202) 606–5000, ext. 340. T.D.D. (202) 565–2799. This proposed rule may be requested in an alternative format for persons with visual impairments.

**SUPPLEMENTARY INFORMATION:** Pursuant to the National and Community Service Act of 1990, as amended (42 U.S.C. 12501 *et seq.*), the Corporation for National and Community Service (''the Corporation''), through the National Service Trust, provides education awards and qualified student loan interest benefits to AmeriCorps participants who successfully complete a term of service in an approved national service position. The AmeriCorps education award may be used to pay for specified educational costs and to repay certain types of student loans. In addition, upon a participant's successful completion of a term of service, the National Service Trust will pay the interest that accrued during the term on certain types of student loans.

On July 12, 1999 (64 FR 37411), we published final rules governing the AmeriCorps education award and related interest benefits. This notice of proposed rulemaking proposes to clarify one provision regarding eligibility for a pro-rated education award and another provision concerning the use of the education award to pay current educational expenses.

### Release for Compelling Personal Circumstances

A participant who demonstrates that compelling personal circumstances make completion of the term of service unreasonably difficult or impossible may be eligible for a pro-rated education award. In the final rule published on July 12, 1999, we listed examples of situations that could be properly classified as compelling personal circumstances. The proposed rule would eliminate one of the situations listed as an example of compelling personal circumstances. Specifically, we propose to rescind our previous determination that compelling personal circumstances are present when a participant, who is serving in a program that includes in its approved objectives the promotion of employment among participants, leaves a term of service to accept an employment opportunity. We believe that eliminating this category is