

## **HCFA's Proposed Rule for External Quality Review of Managed Care Plans: Summary, Analysis and Recommendations**

National Health Law Program  
December 23, 1999

### **Introduction:**

On December 1, 1999, the Health Care Financing Administration published a Notice of Proposed Rulemaking in the Federal Register establishing requirements and procedures for External Quality Review (EQR) of Medicaid managed care organizations (MCOs). The rule implements sections 1932(c)(2) and 1903(a)(C)(ii) of the Social Security Act which were enacted in sections 4705(a) and 4705(b) of the Balanced Budget Act (BBA) of 1997. Under the statute, each contract with a State Medicaid 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.

The proposed rules define EQR, establish qualifications for EQR organizations, identify activities related to external review and address when MCOs may be exempt from EQR activities under statutory provisions designed to minimize duplicative reviews of health plans. Overall, the proposed scheme builds upon requirements set forth in HCFA's September proposed rulemaking implementing requirements for MCOs under the BBA. A major focus of EQR is to validate data generated from performance measures reported to the state by the MCOs and to validate MCOs' performance improvement projects. Major weaknesses of the proposed rules include the failure to: (1) identify a core set of measures or standards that must be tracked and evaluated for all MCOs, (2) mandate standardized protocols or methodologies for doing so, and (3) establish criteria to minimize over-reliance on private accreditation and deeming as a substitute for EQR.

The National Health Law Program will be submitting comments on the proposed rules based on the analysis presented in this draft. We welcome your feedback. You also may indicate your interest in signing on to our comments by returning the form below, or your organization may use this analysis to generate your own comments. Comments are due no later than 5 p.m. on January 31, 2000. Written comments (1 original and 3 copies) should be mailed to: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-2015-P, P.O. Box 7517, Baltimore, MD 21207-0517, or copies may be delivered to Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C.

Yes, my organization will sign onto NHeLP's comments regarding HCFA's proposed rules for external quality review of Medicaid managed care plans.

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## **SUBPART A - General Provisions**

### **1. Basis, scope and applicability - Proposed 42 C.F.R. § 438.1**

#### **Description of the rule:**

This provision states that the statutory basis for this part is section 1932(c)(2) of the Act. This part sets forth the requirements for annual External Quality Reviews (EQR) of each contracting Managed Care Organization (MCO) and establishes that these requirements are applicable to MCOs, prepaid health plans (PHPs) and entities with comprehensive risk contracts that have been exempted by statute from the requirements of section 1903(m)(2)(a).

#### **Discussion of rule:**

Under the statute, every MCO must undergo an annual external quality review. Using its authority under section 1902(a)(4) to establish requirements necessary for the proper and efficient operation of the plan, HCFA proposes that PHP and other comprehensive risk contracts that are exempt from Medicaid managed care requirements under section 1902(m)(2)(b) must be subject to the requirements of an annual, external quality review. HCFA has specifically invited comment about its decision to apply EQR standards to PHPs and other exempt organizations.

We support HCFA's decision to extend EQR to PHPs and other exempt managed care organizations identified in section 1902(m)(2)(B). Many specialty carve-out services such as behavioral health and dental care are provided through PHP arrangements. Some PHPs are very large. For example, the Massachusetts Behavioral Health Partnership operates statewide and is supposed to provide services to over 400,000 people. Extension of EQR requirements to PHPs and other exempt managed care organizations not only promotes quality, but promotes efficiency by helping to standardize how states monitor the quality of care and services provided to beneficiaries regardless of the technical structure of the contracting organization. Further, extension of EQR requirements to PHPs and other exempt organizations is consistent with HCFA's approach in the September 29, 1998 NPRM to extend other BBA consumer protections to these organizations.

#### **Recommendations:**

We fully support HCFA's decision to extend EQR to PHPs and other exempt organizations identified in section 1902(m)(2)(B).

## 2. Definitions - Proposed 42 C.F.R. § 438.2

**Description of rule:** This section sets forth various definitions used throughout the subpart, including:

*External quality review (EQR)* 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 (EQRO)* means “an organization that meets the competence and independence requirements set forth {in the rule} 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.”

### **Discussion:**

Overall, these definitions reflect a narrow, outcome focused, data driven view of external quality review. Specifically, defining EQR as “the analysis and evaluation of *aggregated* information on timeliness, access and quality” suggests that the function of an EQRO is to crunch numbers reported to it either by various entities within the state or by the MCOs themselves. The definition further suggests that EQROs should not be involved in the direct collection of information through a variety of methodologies including patient record reviews, consumer interviews, review of complaint information and focused studies. It is unclear whether HCFA intended this definition to be so construed. We note that section 438.358 lists a much broader array of activities, while section 438.370 states clearly that Federal Financial Participation (FFP) at the enhanced 75 percent match rate is available for expenditures for EQR (including *the production* of EQR information, performed by EQROs or their subcontractors.)” We believe readers, including states, will be confused by these apparent contradictions.

We also believe that the term “quality” is defined too narrowly. From a consumer perspective, quality is much more than just maintaining or improving demonstrable health outcomes. For example, a health plan might demonstrate that it has reduced rehospitalization of its members who have serious and persistent mental illness, but if it has done so primarily by over-reliance on medications, clearly most consumers and their families would not rate the health plan highly in terms of quality. Similarly, a health plan might be able to demonstrate it has increased the rate at which children are immunized, but if it has done so through coercive or unethical means, (i.e.

threatening to turn in immigrant parents who do not bring their children in for shots), then again, most would agree that the health plan is not providing quality care. While these two examples may seem like extremes, we believe that there is a grave danger in defining quality in such a one dimensional way, especially when outcome measures may be tied directly or indirectly to performance bonuses and reimbursement.

Another problem with HCFA's definition is that it focuses solely on health outcomes. Again, from the consumer's perspective, the most important determinants of quality may have to do with non-clinical measures, e.g., waiting times, ease of obtaining referrals and geographic and physical accessibility.

Finally, defining quality solely in terms of health outcomes is not adequate to address the multi-faceted needs of people who have chronic and disabling conditions, especially when the disease course is degenerative or there is little likelihood of demonstrable improvement.

### **Recommendations:**

- L For clarity, HCFA should amend the definition of EQRO as follows:

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

- L HCFA should amend the definition of quality to include measures of consumer satisfaction with non-clinical as well as clinical functions and to incorporate notions of quality that are meaningful to people who have chronic and disabling conditions. We strongly recommend that HCFA convene focus groups of consumers, including people with disabilities and families of children with disabilities, to identify how quality should be defined from the consumer's perspective.

**SUBPARTS B through D reserved**

## **SUBPART E - External Quality Review**

### **1. State responsibilities - Proposed 42 C.F.R. § 438.350**

#### **Description of rule:**

Under this proposed rule, states must ensure that: (1) an annual EQR is performed by a qualified EQRO for each contracting MCO; (2) the EQRO has certain specified information to carry out the review; (3) that the specified information is obtained through methods that are consistent with protocols specified in the rule and (4) the results of the review are made available as specified in the rule.

#### **Discussion:**

The rule broadly outlines the states' responsibilities. No reference is made, however, to HCFA's September NPRM and the proposed "state quality strategy," (proposed 42 CFR §§ 438.300-304), or to the proposed standards for managed care plans (proposed 42 CFR §§ 438.306-342). At the very least, states should be responsible for ensuring that ERQ activities are coordinated with the state's quality assessment and improvement strategy and that minimally, EQR activities evaluate compliance with the standards for timeliness, access and quality that have been (or will be) established by regulation.

#### **Recommendations:**

- L Add to state responsibilities requirements that: (1) EQR activities are coordinated as part of the state's quality strategy established under 42 CFR or § 438.300-304; (2) EQR activities evaluate compliance with the standards established at 42 CFR or § 438.306-342.

### **2. EQR Protocols - Proposed 42 C.F.R. § 438.352**

#### **Description of the rule:**

This provision states that each protocol must specify the data to be gathered, the sources of the data, the detailed procedures to be followed in collecting the data to promote accuracy, validity and reliability, the proposed method or methods for collecting, analyzing and interpreting the data once obtained; and all instructions, guidelines, worksheets and other documents or tools necessary for implementing the protocol.

## Discussion of the rule:

Under the statute, the Secretary is directed to “contract with an independent quality review organization to develop protocols *to be used* in external independent reviews conducted . . . on or after January 1999.” Section 1932(c)(2)(A)(iii)(emphasis added). As drafted, however, the proposed rule allows states to develop their own external review protocols. No reference is made to the protocols being developed by the JCAHO under contract to HCFA, although the preamble states that “[a]ll activities that provide information for EQR must use protocols that are consistent with those that we specify.” 64 Fed. Reg. 67227.

## Recommendations:

- L We agree that the protocols should not be promulgated as a regulation because of the need to keep them current with best practices in the field. Nevertheless, we believe that before the protocols are finalized, HCFA should provide opportunity for public comment. Although HCFA convened an expert panel to review the protocols as they were being developed by JCAHO, consumer participation was very limited. Soliciting more public comment from a broader spectrum of interest groups will serve to improve the protocols and ensure their relevance and usefulness in the EQR process.
- L Once finalized, HCFA clearly must mandate their use by states. Use of the protocols promotes efficiency, lessens burden on the states and promotes the development of standardized data and information about services provided in Medicaid managed care. (We note that without standardized protocols and requirements for nursing facilities, HCFA would not have the tools to monitor effectively quality in our nation’s nursing homes). We also believe that HCFA must mandate their use to be in compliance with the statute.
- L HCFA must ensure that protocols are developed to address the mandated EQR activities identified at section 483.358(a)(2). Pursuant to this section, EQR must determine the MCO’s compliance with state mandated standards in 13 different areas. The current draft protocols do not provide any guidance or framework regarding how an EQRO is supposed to conduct such reviews or make such evaluations.
- L HCFA can promote state flexibility by making clear that the protocols establish *minimum* requirements; states can do more and are not prohibited from developing new approaches.

### **3. Qualifications of EQROs - Proposed 42 C.F.R. § 438.354**

#### **Description of the rule:**

The state must ensure that each EQR is competent and independent.

Competency means that the organization has at least the following:

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

Independence means that 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 -

A State agency, department, university or other State entity may not –

- (1) have Medicaid purchasing or managed care licensing authority;
- (2) deliver any health care services to Medicaid recipients; or
- (3) conduct on the State’s behalf, any other ongoing Medicaid program operations related to oversight of the quality of MCO services.

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.

Finally, an EQRO may not review a particular MCO if either the EQRO or the MCO exerts control over the other as defined in 48 CFR § 19.101.

#### **Discussion of the rule:**

Under the statute, HCFA was required to consult with the States to establish a method for identification of entities that are qualified to conduct EQRs. To HCFA’s credit, it contracted with the National Academy for State Health Policy and convened an expert panel that included

representatives of health plans and consumers. We understand that HCFA incorporated the recommendations of the expert panel regarding the general qualifications of the EQRO. Importantly, the first qualification is that an EQRO have Medicaid expertise. We believe this is essential. We are also pleased that HCFA's definition does not limit the categories of entities that may qualify to be an EQRO or a subcontractor. This gives states greater flexibility and would permit consumer organizations to play a more formal and active role in the monitoring of services.

While we support the proposed rules regarding the qualifications of the EQRO, we do not support how HCFA has defined independence. Under the statute, an EQRO must be independent. This independence is critical to ensuring the integrity of the EQR process and the reliability of findings.

As proposed, HCFA has defined independence to include two elements: independence from the State, and independence from the MCOs they are reviewing. Overall, while HCFA has done a good job of defining circumstances that disqualify a state entity from conducting EQR activities, HCFA gives short shrift to defining disqualifying conflicts of interest for private sector entities. Specifically:

(1) While a state entity may not have Medicaid purchasing or managed care licensing authority (proposed section 438.354(c)(1)(i)), nothing in the rule would prevent a private accrediting firm that reviews and accredits health plans from serving as an EQRO. When states or the federal government rely on private accreditation status to deem health providers such as managed care plans in compliance with state or federal standards, the private accrediting organization is the de facto regulator. In such circumstances, the private accrediting organization has a direct conflict of interest and should not be permitted to serve as an independent EQRO.

(2) While a state entity may not deliver any health care services to Medicaid recipients (proposed section 438.354(c)(1)(ii)), nothing in the rules prevents a private entity that receives Medicaid payments from serving as an EQRO. We submit that any private entity that receives Medicaid payments for services has a direct conflict of interest and should not be permitted to serve as an EQRO for Medicaid managed care.

(3) While a state entity may not conduct, on the State's behalf, any other ongoing Medicaid program operations related to oversight of the quality of MCO services (proposed section 438.354(c)(1)(iii)), nothing in the rule would prevent a private entity that engages in such activity from serving as an EQRO. Perhaps the best example of a private entity that has a conflict of interest due to its ongoing work relating to the oversight of MCO quality is the National Committee for Quality Assurance (NCQA). NCQA, in addition to being a private accrediting organization which markets itself to health plans and to states to promote its own accreditation system, is also the principal purveyor of HEDIS performance measures. While HEDIS is used widely and perhaps sets the industry standard, it is nonetheless, a proprietary

document that NCQA markets and sells. While we do not know what percentage of NCQA revenue is derived from HEDIS, NCQA has a vested interest in promoting HEDIS and demonstrating its usefulness, efficacy and appropriateness for use as a quality management tool for health plans and state agencies. Although a somewhat crude analogy, allowing NCQA to serve as an EQRO is like purchasing a car from a dealer, and then going back to the dealer for an “independent” evaluation of how well the car runs. Despite this obvious conflict of interest, nothing in the rules would prevent NCQA from qualifying as an EQRO.

(4) Only section 438.354(c)(3) addresses potential conflicts between an EQRO and the MCO. This regulation would prohibit an EQRO from reviewing a particular MCO if either the EQRO or the MCO exerts control over the other as defined in 48 C.F.R. § 19.101, a regulation relating to federal acquisitions and small business programs. 48 C.F.R. § 19.101 defines control in three ways: (1) control through stock ownership, (2) control through common management, and (3) control through contractual relationships. While these are useful concepts, the actual definitions in the regulation have little relevance to the potential organizational relationships between EQROs and MCOs in the Medicaid program. For example:

“Control through stock ownership means that the party controls or has the power to control 50 percent or more of the concerns voting stock.” In the Medicaid managed arena, many of the MCOs and most of the private entities that might be interested in serving as EQROs are not publicly traded companies, but non-profit organizations governed by boards of directors.

“Control through interlocking management” means when “officers, directors, employees, or principal stockholders of one concern serves as a working majority of the board of directors or officers of another concern.” Under this definition, a non-profit entity that is governed by a board of directors, the majority of whom are the CEOs of the nation’s largest Medicaid managed care contractors, would not be disqualified to serve as an EQRO.

“Control through contractual relationships” addresses only situations where entities are bidding on a contract as joint venturers.

(4) While the regulation requires that a State agency or other State entity be governed by a board or similar body the majority of whose members are not government employees (proposed section 438.354(2)), a private entity still meets the test of independence even if the majority of its board members are MCO directors or employees, as long as the board members do not come from the same managed care plan.

## Recommendations:

- L HCFA must strengthen substantially the requirements for EQRO independence.
- L Specifically, HCFA should delete section 438.354 (c)(3). In its place, HCFA should promulgate regulations that define what it means for a private entity to be independent that are similar to the regulations at section 438.354(c)(1). For example:

New section 438.354(c)(3)

A private entity may not —

- Have managed care licensing authority, including the authority to certify managed care plans in compliance with standards that serve as the basis for deemed certification with Federal or state regulatory standards.
- Deliver any health care or related services to Medicaid recipients for which it is paid by the Medicaid state agency or by a managed care plan. Related services include enrollment services, grievance resolution, external review of health care coverage decisions or other similar activities.
- Conduct, on the State's behalf, any other ongoing Medicaid program operations related to oversight of the quality of MCO services.
- Have financial interests that would prevent it from exercising independent judgment when engaging in EQRO activities.

New section 438.354(c)(4)

A private entity must be governed by a board or similar body, the majority of whose members are not MCO employees.

## 4. State contract option - 42 C.F.R. § 438.356

### Description of the rule:

This section provides that the State can contract with one or more EQROs as long as they meet the competence requirements. Further, each EQRO can use subcontractors, as long as the EQRO is accountable for and oversees all subcontractor functions. All contractors and subcontractors must meet the requirements for independence as specified in the rule.

Finally, the rule provides that states must use an open, competitive procurement process in accordance with State law and regulations and be consistent with 45 C.F.R. part 74 as it applies to State procurement of Medicaid services.

**Discussion of the rule:**

These provisions give states flexibility to contract with more than one entity to perform EQRO functions. They also hold the EQRO accountable for subcontractor performance.

**Recommendation:**

We support these requirements.

**5. Activities related to external quality review - Proposed 42 C.F.R. § 438.358**

**Description of the rule:**

This rule sets out both mandatory and optional activities relating to EQR. Under mandatory activities, HCFA is proposing that each year, for each MCO, the EQR must use information obtained from validation of performance improvement projects that were required by the State and were performed during the preceding 12 months, and validation of performance measures that the State required and that the MCO reported during the preceding 12 months.

In addition, each year the EQR must also use information obtained from a review, conducted within the previous three year period, to determine the MCO's compliance with standards established by the State for the following 13 areas:

- (1) Availability of services
- (2) Continuity
- (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
- (13) Mechanisms to detect both underutilization and overutilization of services as part of the quality assessment and performance improvement programs.

HCFA further proposes that the review may also use information from the following optional activities:

- (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 [sic] services at a point in time.

HCFA also proposes that the EQRO, at the state's direction, may 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.

#### **Discussion of the rule:**

Under the statute, *every* contract with a Medicaid managed care organization must provide for an annual, independent external review of “quality outcomes and timeliness of, and access to, the items and services for which the managed care organization is responsible under the contract.” We read this to require EQRs to focus on evaluating the services that are supposed to be provided to managed care enrollees under the contract that the state has entered into with the managed care organization.

The proposed rules require EQRs to engage in two mandatory processes. The first required activity is that the EQR *must* use information obtained from both validation of state-mandated performance improvement projects and validation of state-mandated performance measures. Section 438.358 (a)(1). We understand from the preamble that the reference to performance improvement projects and performance measures relates back to HCFA's September NPRM implementing the bulk of the Balanced Budget Act managed care requirements. There is, however, no explicit cross-reference to the relevant section of the September rulemaking.

The rule also does not clearly identify what entities are qualified and competent to undertake the validation of performance improvement projects and performance measures. As drafted, the rule could be interpreted as allowing entities other than the EQRO, including the state or the MCO itself, to undertake these tasks. To avoid conflicts of interest and ensure the integrity of the process, HCFA must clarify that only qualified, independent entities may validate performance improvement projects and performance measures.

Even if HCFA clarifies what entities are qualified to validate the data that is generated by an MCO as a result of its internal quality improvement activities, nothing in the current rulemaking explicitly identifies what the EQR is supposed to do with that information, once it is obtained, or how this information relates to a review of “the quality outcomes and timeliness of, and access to, the items and services for which the managed care organization is responsible under the contract.” In short, we question how proposed section 483.358(a)(1) fulfills the statutory requirement of external quality review. We are also unclear whether the validation of performance improvement projects and performance measures is considered an EQR activity reimbursable at the enhanced 75 percent FFP rate.

Section 438.358(2), defining the second mandatory activity, is somewhat less ambiguous. It provides that the EQR must also use information obtained through various *reviews to determine the MCO’s compliance with state mandated standards*. The rule itself, however, does not identify what state mandated standards (or how many) must be monitored. Again, we assume that HCFA is referring to the standards for access to care, structure and operations and measurement and improvement standards that states will be required to establish once the September NPRM is promulgated as a final rule. See proposed 42 C.F.R. §§ 483.306-.343. However, there is no explicit cross-reference to these standards in this rulemaking.

Beyond the need for clarification, we have two overarching and more serious concerns. First, HCFA has chosen to give states flexibility to set their own performance and quality improvement standards and to design their own protocols for determining compliance with those standards. According to the September NPRM, performance improvement projects are MCO initiatives that measure performance using objective quality indicators, involve interventions to improve quality, evaluate the effectiveness of the interventions and increase or sustain improvement. However, the State gets to determine how many and in which areas MCOs must conduct performance improvement projects. The State also sets minimum performance levels, albeit using standardized performance measures. Again, the State has discretion to set as many or as few as it wishes in whatever areas it chooses. Therefore, little of the data, if any, produced at the plan or state level will be comparable to any other data produced by any other plan or state. In the end, notwithstanding all the pages of regulations and despite a heavy investment of time and resources to develop states’ capacity to collect, track and analyze data, the information produced will have limited value. Ultimately, we will still not be in a position to understand how managed care is or is not meeting the needs of the Medicaid population, or how differences in state and MCO approaches are affecting outcomes.

We know from our experience in long-term care, that the Federal role in setting nationwide minimum standards and establishing standardized methodologies to monitor those standards has greatly enhanced our knowledge about nursing home quality, and has resulted in even greater efforts to improve quality of care. There is no less need for HCFA to take an active leadership role in the managed care arena.

Second, HCFA also has not adequately explained its rationale in section 483.258(a)(2) for permitting states to use data and information that may be up to three years old to determine MCO compliance with a roster of standards relating to the availability, timeliness and access to services. We suspect that allowing states to use three year old data is tied to the accreditation periods of the major accrediting organizations such as NCQA and JCAHO. Given the volatility of both the managed care market and state Medicaid programs, the very real problems that have been identified in Medicaid managed care systems throughout the country, and the fact that the vast majority of beneficiaries enrolled in managed care are children, allowing states to conduct EQR using three year old data is wholly inadequate. EQR is not intended to be an academic exercise but a mechanism for ensuring quality and improving accountability. If an evaluation of quality, timeliness and access to services is not timely, there cannot be effective interventions to correct the problems. Finally, we note that the statute requires an *annual* review. We read the parenthetical “(as appropriate)” to allow states to conduct reviews more frequently, not less frequently. Thus, if a plan’s annual review identified problems, the EQRO could be authorized to conduct follow-up evaluations, as appropriate, to ensure progress toward compliance.

**Recommendations:**

- L Clarify how EQR is supposed to use and evaluate information from validation of performance improvement projects and validation of performance measures.
- L Identify what performance improvement projects and performance measures are to be validated and used.
- L Clarify what types of entities can engage in validation activities. At a minimum, HCFA should require such entities to be competent and independent.
- L Clarify whether validation activities are reimbursable at the 75 percent enhanced FFP rate for EQR activities.
- L Explicitly establish and identify a core set of state standards for MCOs that must be evaluated during the EQR process.
- L Eliminate language in section 438.358(a)(2) that allows the EQR to use information obtained from a review conducted within the previous three year period to determine the MCO’s compliance with state standards. Make clear that the review of state standards must be annual.
- L We support HCFA’s decision to restrict the ability of EQRO entities to serve as consultants to individual MCOs.

## 6. Nonduplication of mandatory activities - Proposed 42 C.F.R. § 438.360

### Description of the rule:

This rule provides that to avoid duplication, the State may exempt an MCO from mandatory activities if certain conditions are met. Specifically, the state may exempt an MCO from determining compliance with state specified standards under section 438.358(2)(a), but not the mandatory activities of section 438.358(a)(1), if:

(1) the MCO is a certified Medicare+Choice organization with a current Medicare contract, *and* the MCO's current structure and its compliance with the standards established by the State have been evaluated and approved by HCFA or its contractor; or

(2) 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). In addition, the MCO must provide to the State all the reports, findings, and other results from the Medicare review or the private accreditation survey. These will be forwarded by the State to the EQR.

The State also has the option of exempting an MCO from both the mandatory activities of sections 438.358 (a)(1) and (a)(2) if the MCO serves only dual eligibles (people who receive both Medicaid and Medicare), the Medicare review activities are substantially comparable to the State specific mandatory activities in sections 438.358(a)(1) and (a)(2), and the MCO provides to the State all the reports, findings and other results of the Medicare review. Again, these findings will be provided by the State to the EQRO.

### Discussion of the rule:

The statute provides that States have the option to exempt a Medicaid managed care organization from duplicative external review activities if the MCO is either accredited by a private, independent entity or has had an external review conducted under the Medicare+Choice program. Unlike deeming in the Medicare program, this statute only authorizes states to eliminate those aspects of external review that duplicate aspects of other review processes. We read this to mean that states should only be allowed to eliminate elements of the EQR process if they are the same or substantially similar to components of a private accreditation or Medicare+Choice EQR evaluation process. Being the same or similar requires both an evaluation of the substance and the methodology. In other words, two questions must be asked: (1) Does this element of Medicaid EQR address the same or substantially similar standard or requirement being address by the accreditation agency or the Medicare+Choice EQR process; and (2) is the evaluation of this issue undertaken by the same or substantially similar methodologies?

HCFA, however, has taken a different approach. Specifically, HCFA would permit a state to eliminate all of the mandatory EQR review of compliance with state mandated standards in section 438.358(a)(2) (but not the evaluation of performance improvement projects or performance measures in section 438.358(a)(1)), if the MCO is a certified Medicare+Choice organization with a current Medicare contract and it meets either of the following conditions: (1) the MCO's structure and its compliance with the standards established by the State under section 438.3548(a)(2) have been evaluated and approved by HCFA or its contractor, or (2) 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 in section 438.358(a)(2). There are several problems with this approach. First, it is unclear when or under what circumstances HCFA or its contractor would have reason to evaluate an MCO for compliance with state standards. Second, assuming that HCFA or its contractor would undertake such reviews, we believe that to serve as a substitute for EQR, the review must be timely, e.g., within the annual review period. Third, the term "at least as stringent" is an ambiguous standard and does not ensure that only duplicative review of standards is eliminated. Fourth, it is the individual state and not HCFA that establishes the standards for the mandatory activity under section 438.358(a)(2). Therefore, it is unclear what benchmark HCFA intends to use.

HCFA also proposes allowing the State to exempt an MCO from *all* mandatory activities if the MCO serves only dually eligible beneficiaries and the Medicare review activities are substantially comparable to the State specified mandatory activities in section 438.358(a)(1) and (a)(2). Again, we believe that before an MCO can be exempted from all EQR activity, a determination must be made that the review standards *and* the review process are the same or substantially similar.

Finally, we believe that HCFA must make clear a state may still undertake optional EQR activities (as long as they are not duplicative of other activities), even if it has exempted an MCO from a portion of or all of the mandatory activity listed in section 438.358(a).

### **Recommendations:**

- L Clarify in the preamble and in the rule that states may only eliminate elements of the EQR process, whether mandatory or optional, if they are the same or similar to components of a private accreditation or the Medicare+Choice EQR evaluation process.
- L Eliminate the reference to "at least as stringent" in section 438.360Ib)(2)(ii). Instead, clarify that being the same or similar requires both an evaluation of the substance and the methodology. In other words, two questions must be asked: (1) Does this element of Medicaid EQR address the same standard or requirement being address by the accreditation agency or the Medicare+Choice EQR process;

and (2) is the evaluation of this issue undertaken by the same or similar methodologies?

- L In section 483.360(b)(ii), clarify that private accrediting standards and methodologies must be the same or substantially similar to the standards established by the state, not HCFA, under section 483.358(a)(2).

## **7. Exemption for external quality review - Proposed 42 C.F.R. § 438.362**

### **Description of the rule:**

This rule provides that States may exempt an MCO from all EQR requirements if: (1) the MCO has a current Medicare+Choice managed care contract and a current Medicaid managed care contract; (2) the two contracts cover all or part of the same geographic area; and (3) the Medicaid contract has been in effect for at least two years and during those two years the MCO has been subject to EQR and found to be performing acceptably with respect to the timeliness, access and quality of health care services it provides to Medicaid recipients.

### **Discussion of the rule:**

This rule closely follows the statute allowing an MCO that has both Medicare and Medicaid managed care contracts to be exempt from Medicaid EQR if it has had a Medicaid contract in effect during the previous two year period. HCFA has added the requirement that the two contracts cover the same geographic area and that the Medicaid plan have a demonstrated track record of compliance. We believe that these additional requirements are the minimum requirements necessary to ensure that Medicaid MCOs are held accountable to provide quality care under their contracts to Medicaid beneficiaries. We note that Medicare+Choice plans serve markedly different populations, provide different benefit packages and often, offer different provider networks. It would be unconscionable to allow an MCO with both Medicaid and Medicare managed care contracts to be exempt from Medicaid EQR solely based on the fact that it operates under two different contracts. In addition, before exempting a plan from Medicaid EQR under this rule, HCFA should require that the two plans operate with substantially similar provider networks and provide similar benefits and services.

### **Recommendations:**

- L We fully support requiring MCOs that operate both Medicare+Choice and Medicaid managed care plans to demonstrate a track record of compliance before being exempted from Medicaid EQR.
- L We fully support requiring that the MCOs operate in the same geographic area.
- L We recommend that HCFA also require MCOs to demonstrate that the Medicare and Medicaid plans operate with the same provider networks and offer the same or substantially similar benefits and services.

## **8. External quality review results - Proposed 42 C.F.R. § 438.364**

This rule provides that the state must ensure that the EQR produces at least: (1) a detailed technical report, (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 quality furnished by the MCOs, (4) as the state determines methodologically appropriate, comparative information about all MCOs, and (5) an assessment of the degrees to which each MCO has effectively addressed the recommendations for quality improvement made during the previous year. The detailed report must include objective, technical methods of data collections and analysis, data obtained and conclusions drawn from the data.

The rule also specifies that the State must provide copies of the information, upon request, to interested parties including health care providers, enrollees and potential enrollees and advocate groups and members of the general public. However, information released may not disclose the identity of any patient.

### **Discussion of the rule:**

This rule implements the statutory requirement that EQR results be made available to interested parties. We are very pleased that HCFA has broadly defined the information that must be disclosed upon request. We believe that public access to information about quality is necessary to ensure that consumers can make informed choices about their health care. It also is critical to ensuring accountability and improving public confidence in oversight processes.

There is, however, a need to clarify one important issue with respect to access to information. We note that while HCFA has specified in section 483.360 that MCOs must submit all of the private accreditation surveys and findings to the State, and the State is responsible for giving it to the EQR, HCFA has not addressed whether those findings, once submitted to the state, become information available to the public. Without up-front clarification, we anticipate that private accrediting organizations, MCOs and even States, will resist the public release of EQR review results that have been based, in whole or in part, on private accreditation processes. We also believe that private accrediting organizations will not allow the release of the underlying technical specifications, data and the detailed assessments used in the evaluative process. We believe that as a *quid pro quo* for eliminating duplicative requirements based on private accreditation, HCFA must ensure that private accreditation decisions, detailed information from the surveys, as well as the accreditations standards and protocols used are available to the public to the same extent that EQR information must be disclosed under section 438.364. The President's Advisory Commission on Consumer Protections and Quality in the Health Care Industry similarly has recommended that when private accreditation is used, there must be full

disclosure of the standards, survey protocols, and detailed information from the surveys. *See Quality First: Better Health Care for All Americans, Final Report to the President of the United States* at 149-50.

**Recommendations:**

- L We applaud HCFA's efforts to ensure public access to EQR information.
- L HCFA must clarify that if an MCO is exempted from EQR based in whole or in part upon a private accreditation process, information submitted to the state under section 483.360((b)(3) is subject to disclosure under sections 483.364(a) and (b).

**9. Federal financial participation - Proposed 42 C.F.R. § 483.370**

**Description of the rule:**

This rule provides that FFP at the 75 percent rate is available for expenditures for EQR including the production of EQR information, performed by EQROs and their subcontractors. The rule also provides that FFP at the 50 percent rate is available for expenditures for EQR-related activities performed by any entity that does not qualify as an EQRO.

**Discussion:**

This rule makes clear that states are still free to contract with organizations that fail to meet the qualifications for an EQRO to conduct EQR activities. We believe that HCFA must make clear that if a state contracts with an entity that is not qualified as an EQRO, it has not fulfilled its obligation under the law to ensure that every MCO is subject to an annual external review. In addition, assuming the work is an allowable administrative expense, it can only be reimbursed at the non-enhanced FFP rate for administrative expenses.

**Recommendations:**

- L Clarify that a state cannot fulfill its statutory obligations to conduct EQR by contracting with a non-qualified entity.