

provision required that we contract with an independent quality review organization to develop protocols to be used with respect to EQRs required by statute. In response to the requirement under section 1932(c)(2)(A)(iii) of the Act, we contracted with the Joint Commission on Accreditation of Health Care Organizations (JCAHO) which developed nine protocols and one appendix to several of the protocols in six quality improvement areas. We received 13 comments on the November 23, 2001 **Federal Register** notice. We carefully reviewed and considered all the comments we received.

II. Provisions of the Proposed Rule and Discussion of Public Comments

A. Basis, Scope and Applicability. (Formerly § 438.1), (Now § 438.310)

In this section we proposed to apply provisions to MCOs, prepaid health plans (PHPs), and entities with comprehensive risk contracts that are exempted by statute from the requirements in section 1903(m) of the Act, health insuring organizations (HIOs).

Comment: Many commenters supported the application of this rule to all three of the above types of entities. One commenter, though not opposed to the inclusion of PHPs, expressed concern about the cost of this requirement when applied to entities that provide services to small populations. The commenter suggested that the regulation apply only to entities to the extent feasible for the study being performed. Another commenter did not agree that the provisions should apply to PHPs and stated that there is no specific reference in Federal law to these organizations and that we have gone beyond the explicit language in section 1932(c) of the Act.

Response: We continue to believe these provisions should apply to most capitated health plans that are not MCOs, but that provide inpatient services. The Medicaid managed care final rule eliminated the term PHP and replaced it with two types of entities—prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). That rule, under the authority of section 1902(a)(4) of the Act, which authorizes the Secretary to establish requirements necessary “for proper and efficient operation of the plan,” applies the provisions related to a State’s quality strategy to PIHPs but not to PAHPs. It does not apply these quality provisions to PAHPs because these entities provide a more limited array of services (for example, transportation or dental), and we do not believe it

appropriate to require States to include these entities in their State quality strategies due to the burden it would impose. We, therefore, are revising this rule to be consistent with the Medicaid managed care final rule (§ 438.204(d)) and apply the EQR provisions to PIHPs as specified at § 438.310. We have also made changes to clarify the applicability of this rule to HIOs to be consistent with the Medicaid managed care final rule.

We do not agree with the commenter that we should exempt entities that have smaller enrolled populations from these requirements. Sections 1932(c)(2)(B) and (C) of the Act specifically identify the circumstances under which an entity may be fully or partially exempt from EQR.

Comment: One commenter asked if we intend to hold Indian Health Services (IHS) and 638 Tribal Facilities to the same standard as MCOs to ensure the quality of care provided to Native Americans.

Response: If an IHS entity or 638 Tribal Facility meets the definition of an MCO or PIHP, it would be subject to these provisions.

Comment: One commenter does not believe that primary care case management (PCCM) programs should be subject to these requirements. Another commenter believes that the activities in the December 1, 1999 proposed rule should be applied to PCCM programs.

Response: The statute does not extend the EQR requirement to PCCMs and the Conference Report, pages 859–860, makes clear that PCCMs were specifically excluded from the requirements. We have used the authority of section 1902(a)(4) of the Act to extend the EQR provision to PIHPs because, like MCOs, PIHPs provide inpatient services and are capitated. If a PCCM meets the definition of a PIHP, then it would be subject to the provisions of this rule. However, traditional PCCMs are reimbursed on a fee-for-service (FFS) basis along with a case management fee. Under that reimbursement arrangement, the PCCM would not be subject to the EQR requirements.

Comment: Many commenters recommended that external review also examine subcontracting managed care entities. One commenter suggested that the definition of quality be expanded to include services provided through subcontracts with MCOs.

Response: The MCO or PIHP is fully responsible (§ 438.230 of the Medicaid managed care final rule) for all activities delegated to another entity. Therefore, the EQR should include information on all beneficiaries and the structure and

operations of all entities that provide Medicaid services under either the prime contract or subcontract. At § 438.320, we revised our definition of EQR to clarify our intent that the EQR provisions apply to all services received by Medicaid beneficiaries regardless of whether those services are provided by the MCO or PIHP directly or through a subcontract.

Comment: One commenter is concerned that this rule applies the EQR requirement to PHPs despite the BBA’s statutory reference only to organizations under section 1903(m) of the Act. The commenter asked us to clarify whether we intend to apply these requirements to any entity that is paid on a prepaid capitation basis for services furnished to enrollees, even if the PHP is not at any financial risk for those services.

Response: As noted in an earlier response, the EQR provisions will apply to a PIHP defined in the Medicaid managed care final rule as an entity that “provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangement that do not use State plan payment rates and that provides, arranges, or otherwise has the responsibility for the provision of any inpatient hospital or institutional services for its enrollees * * *.” We do not apply these quality provisions to PAHPs because these entities provide a more limited array of services (for example, transportation or dental), and we do not require States to include these entities in their State quality strategies due to the burden it would impose. The application of this rule to PIHPs is not based on section 1903(m) of the Act. It is based on section 1902(a)(4) of the Act that authorizes the Secretary to establish requirements necessary “for the proper and efficient operation of the plan.” We believe this is consistent with congressional intent.

PIHP and PAHP designation is not based on whether an entity is at financial risk for services provided. Designation is based on prepaid capitation payments for a scope of services. Even though there will be few PIHPs that are not at financial risk, due to the scope of services these entities provide (for example, inpatient services), we believe they should be subject to EQR provisions.

B. Definitions (Formerly § 438.2), (Now § 438.320)

This section of the proposed rule defined “EQR” and “EQRO.” It also defined the terms “quality” and “validation” as they pertain to EQR.