

independent assessment under section 1915(b) of the Act is the State's managed care program as a whole, not individual MCOs or PIHPs. In contrast, the EQR review is a review of individual MCOs and PIHPs. The EQR requirement applies to all MCOs and PIHPs regardless of whether the program is voluntary or mandatory or whether it is authorized under a waiver. Further, EQR is conducted annually, whereas the review under section 1915(b) of the Act is conducted for the first 2-year period of the waiver, and the first renewal period (assuming the review results are acceptable). In addition, the independent assessment that we require in the case of a waiver under section 1915(b) of the Act applies to PCCM programs as well as programs with capitated arrangements. The EQR requirement does not apply to PCCM programs.

Comments: One commenter supported the proposed elimination of the requirement in § 434.53 for a system of periodic medical audits.

Response: While we note that this comment does not directly pertain to this proposed rule, we agree with the commenter. We believe that the system of periodic medical audits under § 434.53 is an out-dated approach to quality assessment and improvement which would be duplicative of EQR activities. (In this sense, the matter is relevant to this final rule.) Consequently, the Medicaid managed care final rule published on June 14, 2002 eliminated this requirement, as well as other regulations in subpart E of part 434.

Comment: Several commenters thought the proposed time period for bringing contracts into compliance with the new EQR requirements did not provide sufficient time for States. One commenter suggested that the new EQR rules apply to contracts entered into or revised on or after 90 days, but no longer than 18 months from the effective date. One commenter believed that States needed more than a year to implement this rule. One commenter recommended implementation of the redrafted rule on January 1 to be consistent with NCQA and other planning cycles and allow up to 180 days before implementation.

Response: To be consistent with the Medicaid managed care final rule, we have retained the effective date of this rule to be 60 days following its publication. However, we have revised the time frame for provisions to be implemented through contracts with MCOs, PIHPs, and EQROs so that they must be effective with contracts entered into or revised on or after 60 days

following the publication date. States have up until no longer than 12 months from the effective date to bring contracts into compliance with the final rule provisions.

M. Collection of Information Requirements: December 1, 1999 Proposed Rule

In the December 1, 1999 proposed rule, we asked for comment on the following provisions that contain information collection requirements: nonduplication of mandatory activities (§ 438.360), exemption from external quality review (§ 438.362), and external quality review results (§ 438.364).

A. General Comments

Comment: One commenter contended that the burden to the MCO of working with the EQRO is not included.

Response: As part of the MCO and PIHP contracts with States, MCOs and PIHPs are required to work with States on a routine basis. This includes working with State contractors. We do not believe that working with EQROs adds burden for MCOs and PIHPs but continue to believe that it is part of the normal course of business for MCOs and PIHPs with Medicaid contracts. Further, a requirement for EQR is not new. It has been in place since the late 1980's under section 1902(a)(30)(C) of the Act.

Comment: One commenter felt that while the financial impact of this rule may be difficult to quantify, the proposed regulations would significantly increase the time and administrative burden on States, EQROs, MCOs, and PHPs well beyond the hourly estimates in the preamble.

Response: We do not agree that the regulation will significantly increase the time and administrative burden of States, EQROs, MCOs, and PIHPs beyond what we estimated in the proposed rule. Through our data and information collection, we know that the EQR-related activities referenced in this rule are those that are already typically required by States. Similarly, MCOs have previously been complying with EQR requirements subsequent to the enactment of section 1902(a)(30)(C) of the Act in 1986.

Section 438.360 Nonduplication of Mandatory Activities

Comment: Several commenters argued that the estimate of the total burden for the State for the proposed nonduplication provisions was too low, and asked how the estimate of 4 hours was determined. One commenter asked what data the MCO would need to provide to the State under proposed § 438.360(b)(2) and (c)(2).

Response: We estimated that it would take State staff approximately 4 hours to collect, copy, and disseminate the reports, findings, and other results of Medicare reviews or information obtained from the accreditation reviews and sent to the State. Because we received several comments indicating that this estimate was low, but commenters did not provide us with what they believe the estimate to be, we have increased the burden hours by 100 percent, to 8 hours. In accordance with § 438.360(b)(3) of the final rule, the MCO or PIHP needs to provide to the State any reports, findings, or results from an accreditation review or our review for Medicare for the standards in § 438.204(g) that are being substituted in place of a Medicaid review. In addition, if the MCO or PIHP provides services to dually eligible individuals and the State allows the MCO or PIHP to provide information from a Medicare review of performance measures and performance improvement projects for the EQR in place of separate Medicaid measures and projects, under § 438.360(c)(3), the MCO or PIHP will need to provide the results of Medicare review activities to the State.

Section 438.362 Exemption From External Quality Review

We did not receive any comments on the information collection burdens associated with complying with this provision.

Section 438.364 External Quality Review Results

Comment: One commenter noted that the preamble of the proposed rule addresses the burden of disseminating information, but not of creating the content listed. The commenter believed that the burden for creating the information required to comply with § 438.364(a)(2) would be significant, and would serve no purpose other than to comply with the rule. The commenter recommended deleting § 438.364(a)(2). Several commenters argued that the effort to compile and aggregate the data, analyze, and formulate the review reports will take a significant number of hours above the estimated number.

Response: The proposed rule did not address the burden of conducting EQR activities, because we had not completed the protocols at the time the proposed rule was published. A request for comment on the information collection requirement burden of the protocols was solicited in our November 23, 2001 **Federal Register** notice. We did, however, address in the proposed rule the burden associated with creating the EQR results report. We estimated