

included these cross-references in the December 1, 1999 proposed rule as the Medicaid managed care final rule had not yet been published.

We have added a general rule under paragraph (a) to clarify that the mandatory and optional EQR related activities can be conducted by the State, the State's agent that is not an MCO or PIHP, or an EQRO.

We have revised paragraph (b)(1) to clarify that information from the validation of performance improvement projects that are underway, as opposed to those being performed, must be obtained from the MCO or PIHP. We have revised paragraph (b)(2) to clarify that information on performance measures can be obtained from either those calculated by the MCO/PIHP and validated by the State or its agent, or those calculated by the State on behalf of the MCO/PIHP. We have also revised (b)(3) by eliminating the reference to specific State standards. These are now referenced in the aggregate by our cross-reference to the Medicaid managed care final rule provision. We have also revised paragraph (c) to clarify that information from optional activities must be from information derived within the preceding 12 months.

Section 438.360—Nonduplication of Mandatory Activities

We have revised this section by removing the word "exempt." Using this word caused confusion with the "exemption of EQR requirements" under § 438.362. In its place, we provide language that explains that the nonduplication provisions allow States to use information from either a Medicare or accreditation review for certain standards and activities in place of a Medicaid review.

We have also revised this section to allow States to apply this provision to MCOs and PIHPs that provide health care services to commercial consumers of health care as well as Medicare beneficiaries. We have further revised this section to clarify that national accrediting organizations are those organizations that have been approved and recognized for M+C deeming. We have made this clarification throughout the rule as appropriate.

We have restructured this section by revising paragraph (b) so it applies to both M+C and MCOs and PIHPs that provide services to commercial consumers and have revised paragraph (c) to address additional provisions for those MCOs and PIHPs providing services to dually eligible beneficiaries only. Under paragraph (b) and (c), we have added a provision that requires the State in its quality strategy to identify

those standards and activities for which it will substitute the Medicare or accreditation review for the Medicaid review. In addition, we require the State to explain the rationale for why the State considers the standards or activities duplicative.

Section 438.362—Exemption From External Quality Review

We have revised paragraph (a)(2) to clarify that the Medicare and Medicaid contract must overlap geographically within the State when it exempts the MCO or PIHP from EQR. The December 1, 1999 proposed rule did not require that the overlap be within the State.

We have revised (b)(1) to clarify that information from Medicare reviews is to be obtained by the State from the MCO or PIHP. The language in the December 1, 1999 proposed rule could have been misinterpreted to mean that the State had to obtain the information from CMS or its agent. We have also revised paragraph (b)(2) to clarify that the MCO or PIHP must provide the State a copy of the accreditation review findings as opposed to ensuring the State receives a copy.

Section 438.364—External Quality Review Results

We have revised paragraph (a)(1) to clarify that in the detailed report, conclusions are drawn as to the timeliness of and access to care as well as the quality of care. We have revised paragraph (a)(1)(iii) to clarify that the detailed report should include a "description" of the data obtained for each EQR-related activity as opposed to the data obtained. We did not intend for the raw data to be provided as part of the EQR results. We have also revised paragraph (a)(2) to require an assessment of the MCO's and PIHP's strengths and weaknesses be addressed as opposed to a "detailed" assessment of the MCO's and PIHP's strengths and weaknesses.

We have revised paragraph (b) to require that the EQR results, upon request, be made available in alternative formats for persons with sensory impairments and that the EQR results be made available through electronic as well as printed copies.

Section 438.370—Federal Financial Participation

We have revised (a) to clarify that 75 percent FFP is also available for the production of the EQR results.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to

provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement 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.

Therefore, we are soliciting public comment on each of these issues for §§ 438.352, 438.360, 438.362 and 438.364 of this document that contain information collection requirements.

We published a notice in the **Federal Register** on November 23, 2001, to give the public a 60-day period in which to comment. The basic purpose was to afford the public an opportunity to comment on the protocols. We have addressed the comments received in response to this **Federal Register** notice in section III. above.

For purposes of this requirement, we incorporated Medicaid managed care data from the 2001 Medicaid enrollment report. As of June 2001, there were 329 MCOs (this includes 5 HIOs that must adhere to the EQR requirements of this regulation), and 129 mental health and substance abuse PIHPs.

§ 438.358 (Activities related to EQR)— For each MCO and PIHP, the EQR must use information from the following activities:

(1) Validation of performance improvement projects required by the State to comply with requirements set forth in § 438.240(b)(1) and that were under way during the preceding 12 months.

(2) Validation of MCO or PIHP performance measures reported (as required by the State) or MCO or PIHP performance measure calculated by the State during the preceding 12 months to comply with requirements set forth in § 438.240(b)(2).

(3) A review, conducted within the previous 3-year period, to determine the MCO's or PIHP's compliance with standards (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures, respectively)