

that it would take 160 hours for an EQRO to prepare and submit the EQR results. Since we received several comments stating that it would take more time than the 160 hours we proposed, but commenters did not provide us with time estimates, we are increasing the burden hours by 25 percent.

We do not agree that the burden of § 438.364(a)(2) is significant, or that it serves no useful purpose. We believe that an assessment of the strengths and weaknesses of MCOs and PIHP performance as it relates to the quality, timeliness, and access to health care services was the intent of the statutory provision that requires the results of EQR be made available to beneficiaries and providers. We retain these EQR results provisions in the final rule.

N. Impact Statement

To comply with Executive order 12866 and the Regulatory Flexibility Act we examined the impact of the December 1, 1999 proposed rule. We determined that the net impact of the proposed rule would be below the \$100 million annual threshold, and that a regulatory impact analysis was, therefore, not required.

Comment: Several commenters believed that the proposed rule would result in greater costs and burden to States and MCOs than we estimated in the impact statement. The commenters stated that we did not estimate the increased costs to States and MCOs for external review for compliance with standards. The commenter also felt that we did not consider the negative impact of external auditing on other MCO activities, or new and ongoing infrastructure and labor, needed to comply with these provisions. One commenter contended that these activities would require MCOs and their providers to devote significant staff time to collect, organize, and prepare for review of large quantities of quality assurance data. Another commenter felt that due to the independence requirements, the net results would be that fewer entities would qualify to conduct EQR.

Response: We do not agree with these comments. The only activity that must be conducted by an EQRO is the analysis and evaluation of the information obtained from the EQR activities. If a State chooses to, it can conduct any of the EQR-related activities and receive the 50 percent administrative match as long as the activities are conducted using our protocols or protocols consistent with those we developed. In addition, many States are already conducting or having

State contractors conduct many of the EQR activities. As we stated in our proposed rule, most States are already obtaining a 75 percent matching rate for many of these activities and we, therefore, believe there will not be a significant increase in Medicaid expenditures, and that no new significant infrastructure will be needed. We do not believe that this requirement will cause MCOs to devote significantly more time to collect, organize, and prepare for EQR than is already required by States to ensure compliance with their contracts with MCOs and PIHPs.

Because this will be a new requirement on PIHPs, we acknowledged in the proposed rule that there may be additional cost to the Federal government, since States currently conducting these activities receive a 50 percent administrative match, but under this rule they can now obtain the enhanced 75 percent FFP. We do not believe these costs are significant. Based on an analysis of 2001 Quality Improvement Organization funding on the CMS-64, we estimate a cost of \$5,800,000.

Comment: One commenter, while supportive of holding MCOs accountable by measuring quality of care, noted that there is no such requirement for the Medicaid FFS program, and that these costs are, therefore, not reflected in the rate-setting methodology for managed care plans. This commenter also noted that undertaking these reviews has a significant cost implication for both the MCOs and the State.

Response: The statutory quality assessment provisions implemented in this final rule do not apply to the Medicaid FFS program. Moreover, there is no statutory or legislative history to indicate that the Congress intended that these provisions should apply to Medicaid FFS. The Collection of Information Requirements and Impact Statement address what we believe to be the cost implications of this requirement as it pertains to Medicaid capitated programs. We note that in the Medicaid managed care final rule, a new methodology was adopted for setting capitation rates. This methodology permits States to reflect MCO and PIHP administrative costs (including costs of complying with quality assessment requirements that do not apply under FFS Medicaid) in capitation rates.

Comment: One commenter believed that requiring an independent organization to conduct a review of an MCO's structural and operational standards would add an additional administrative expense to the program.

Response: States currently review MCOs and PIHPs for compliance with State standards. If conducted by the State, this expense is reimbursed at a 50 percent administrative match. However, some States currently define this activity as part of EQR, and thus receive the 75 percent enhanced Federal match. Under the provisions of this rule, if a State chooses to contract with an EQRO to conduct a review of MCO and PIHP compliance with State standards, a State can obtain a 75 percent enhanced match rate. While this may increase Federal expenditures, we do not believe that the increase will be significant, as some States already have their EQROs conduct this activity. Thus, we do not believe this affects our conclusions regarding the need for a regulatory impact analysis.

Comment: One commenter believed that the proposed reporting requirement would increase costs.

Response: States currently have their EQROs develop reports. We believe that this will not add significantly to the current costs incurred by the Medicaid program.

Comment: One commenter believed that our proposed decision to extend EQR requirements to PHPs would increase costs to States, and that we have not fully analyzed this financial impact.

Response: We stated in our proposed rule that applying this provision to PHPs might result in additional costs. Although States are currently conducting a variety of quality activities with their PIHPs and receiving a 50 percent administrative match for their costs, they now may obtain the enhanced 75 percent FFP match for these activities. Again, while this will result in some additional Federal costs, State costs will decline. We do not believe these costs are significant. As stated in a previous response, based on an analysis of 2001 Quality Improvement Organization funding from the CMS-64, we estimate a cost of \$5,800,000.

Comment: One commenter was concerned about the cost of responding to additional EQR requirements, and the potential for duplication and administrative burden to comply with QISMC, the Medicaid rules, and EQR rules.

Response: We do not foresee that there will be any duplication of effort between complying with the BBA provisions, including the EQR provisions, and QISMC. As we stated previously, QISMC has been superseded by the Medicaid managed care final rules that incorporate key elements of the QISMC document.