

agency. We estimate that it will take each MCO 8 hours to disclose the necessary documentation to the State, 4 hours of professional time and 4 hours of clerical time. Therefore, the total burden associated with this requirement is $336 \text{ MCOs/PIHPs} \times 8 \text{ hours} = 2688$ annual burden hours. At \$37.50 per hour (\$12 + \$63/2), the cost will be \$100,800.

This section also requires that a State agency provide the reports, findings, and other results of the Medicare or private accreditation review to the appropriate EQRO. We estimate that it will take, on average, 8 hours for a State to disclose the necessary documentation to the appropriate EQRO. The total annual burden associated with this requirement is 2688 hours (\$37.50 per hour) and \$100,800.

This section also requires a State to include in its quality strategy information concerning the activities or standards for which it is obtaining information from Medicare or an accrediting organization. We believe that the burden for this information collection requirement is included in the burden addressed in the Medicaid managed care rule and approved under OMB number 0938.

§ 438.362 (Exemption from EQR)—Each year, exempted MCOs/PIHPs must provide to the State agency the most recent Medicare review findings reported to the MCO/PIHP. This information must include (1) all data, correspondence, information, and findings pertaining to the MCO's/PIHP's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities; (2) all measures of the MCO's/PIHP's performance; and (3) the findings and results of all performance improvement projects pertaining to Medicare enrollees.

If an exempted MCO/PIHP has been reviewed by a private accrediting organization and the survey results have been used to either fulfill certain requirements for Medicare external review under 42 CFR part 422, subpart D or to deem compliance with Medicare requirements as provided in § 422.156, the MCO/PIHP must submit a copy of all findings pertaining to its most recent accreditation review to the State agency. These findings must include accreditation survey results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

The burden associated with these requirements is not applicable for 2

years following the final publication of this regulation. After 2 years, the time and effort for an exempted MCO/PIHP to disclose the findings of its most recent Medicare or private accreditation review to the State agency will be the burden associated with these requirements. We estimate, of the approximately 202 MCOs that potentially may provide Medicare services in addition to Medicaid services, State agencies will allow for approximately 10 percent of the MCOs to be exempt from the EQR requirement. We further estimate that it will take each MCO 8 hours to prepare and submit the necessary documentation to the State agency. Therefore, the total burden associated with this requirement is 10 percent of $202 \text{ MCOs} \times 8 \text{ hours} = 160$ annual burden hours. At a cost of \$37.50 (\$12 + \$63/2) per hour, we assume a total cost of \$6,000.

§ 438.364 (EQR results)—The EQRO responsible for the EQR function will be required to provide to the State agency a detailed technical report that describes for each mandatory and optional activity undertaken for the EQR, the objectives, technical methods of data collection and analysis, a description of the data obtained, conclusions drawn from the data, and the manner in which the conclusions were drawn as to the quality of the care furnished by the MCO/PIHP. In addition, the report must include: (1) An assessment of each MCO's/PIHP's strengths and weaknesses with respect to the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries; (2) recommendations for improving the quality of health care services furnished by each MCO/PIHP; (3) as the State agency determines methodologically appropriate, comparative information about all MCOs/PIHPs, and (4) an assessment of the degree to which each MCO/PIHP has addressed effectively the recommendations for quality improvement, as made by the EQRO during the previous year's EQR.

The burden associated with this requirement is the time and effort for an EQRO to submit to a State agency a detailed technical report for each EQR conducted. We estimate that it will take an EQRO 200 hours to prepare and submit the necessary documentation to the State agency. Therefore, the total burden associated with this requirement is 458 technical reports ($329 \text{ MCOs} + 129 \text{ PIHPs} \times 200 \text{ hours} = 91,600$ annual burden hours. Assuming wages of \$63 per hour for professionals to comply with this requirement, the cost is \$5,770,800.

This section also requires each State agency to provide copies of technical

reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO/PIHP, beneficiary advocate groups, and members of the general public.

The burden associated with this requirement is the time and effort for a State agency to disclose copies of a given technical report to interested parties. We estimate that on average, it will take a State agency 8 hours to disclose the required information. Therefore, the total burden associated with this requirement is $329 \text{ MCOs} + 129 \text{ PIHPs} \times 25 \text{ requests per MCO or PIHP} \times 8 \text{ hours} = 91,600$ annual burden hours and a cost (\$12 per hour) of \$1,099,200.

The information collection requirements contained in this final rule will be submitted to OMB for review. In accordance with the Paperwork Reduction Act, these requirements will not go into effect until approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail 3 copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850; Attn: Julie Brown, HCFA-2015-F; and
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year).