

detailed and lengthy protocols instead of either guidelines for States or streamlined protocols that specify only the basics for ensuring statistically sound, reliable, and valid results. One of these commenters stated that our intent appears to limit State flexibility and suggested that CMS significantly simplify the protocols to ensure feasibility for State agencies. This commenter also asked that CMS obtain State input on the draft protocols.

Several commenters believed that CMS should require that States use the protocols. One commenter felt that the proposed rule allows States to develop their own external review protocols. This commenter asked CMS to mandate the use of the protocols in order to comply with section 1932(c)(2)(A)(iii) of the Act which directs the Secretary to “* * * contract with an independent quality review organization to develop protocols to be used in external reviews conducted * * *.” The commenter asserted that mandating the protocols would promote efficiency, lessen burden on the States, and promote the development of standardized data and information about services provided in Medicaid managed care.

Response: This regulation provides States with the option to use the protocols developed by us or protocols that are consistent with our protocols. We believe that by allowing States to use “consistent” protocols, States will be able to improve the protocols over time as the state-of-the-art advances and at the same time ensure that reliable and valid methods are used when conducting EQR-related activities.

The protocol documents include a discussion of the activities and steps necessary to soundly conduct the quality assessment function addressed by each protocol. In addition, each protocol includes guidance on how to implement the essential elements of the protocol as well as optional worksheets and appendices that States may use at their discretion. The activities and steps contained in the protocols are generic, relatively brief, but contain the essential components for a methodologically sound review that the statute envisions. Therefore, we believe that the protocols allow for State flexibility while ensuring the methodologically sound and valid EQR.

Comment: Several commenters noted that it is difficult to determine the full extent of the impact of the protocols on EQR activities until they are published. These commenters stated that they hope the protocols will respect States’ individuality and provide flexibility whenever possible to allow for tailoring of EQR activities to local conditions and

circumstances. One commenter further stated that there are many clinical guidelines and protocols that are already published, easily available, and in current use (for example, those developed by the Agency for Health Care Policy and Research (AHCPR) now the Agency for Health Care Research and Quality (AHRQ), American Heart Association, etc * * *) that are not mentioned in the proposed rule.

Another commenter stated that the protocols should be subject to full public scrutiny because they carry the full weight of the regulation. The commenter believes the protocols significantly exceed both the intent of the Congress in the BBA and the proper role of this regulation. Specifically, the commenter noted that the statute does not specify the activities that the protocols should address or other details included. The commenter was also concerned that States will find the 75 percent match for EQR activities a strong incentive to outsource this function, which the commenter believes appropriately rests with the government. As a result, this commenter believes that activities now done by the State according to locally developed protocols will be shifted to contract staff to be performed using externally derived standard protocols.

Another commenter asked that current State practices not be totally dismissed and that consideration be given to the quality improvement system for managed care (QISMC) standards and how they can be incorporated into the EQR process.

Response: We published a notice in the **Federal Register** on November 23, 2001 (64 FR 58741) announcing the completion of the protocols and asking for comment on their burden. At that time, the protocols were also made available on our website. Comments on the protocols and our responses are incorporated in this preamble. We believe the protocols are generic and can be used by all States. They are not clinical protocols like those published by AHCPR (now AHRQ), the American Heart Association, and other organizations. We believe that the protocols are consistent with the intent of the Congress in the BBA. We also note that we have provided States with great flexibility to conduct all EQR-related activities, allowing States to perform EQR-related activities either themselves or through the use of contractors, as long as they are performed consistent with our protocols. While the enhanced Federal financial match for EQR-related activities is not available under the statute if conducted by State personnel,

other provisions of Medicaid law provide for enhanced Federal financial match for qualified medical activities when conducted by State staff who qualify as skilled and professional medical personnel.

The protocols are based on existing protocols already in use in the public and private sector. The contractor used QISMC guidelines as well as other public and private sector protocols in developing all the protocols. With respect to the QISMC standards (as opposed to their interpretive guidelines) we note, for Medicaid, that the QISMC standards were superseded by the Medicaid managed care final rule. QISMC standards are no longer current for the Medicaid program. For each protocol developed, specific information can be found in the protocol regarding which public and private sector protocols were reviewed and the extent to which they were incorporated.

Comment: One commenter was concerned that the JCAHO does not have a traditional background in this area and may take a different approach than NCQA.

Response: The BBA specified that the protocols be developed by an “independent quality review organization.” The JCAHO was selected through an open competitive procurement process, which required them to provide evidence of their experience in protocol development. In addition, they developed the EQR protocols using existing protocols widely used in the public and private sector, including protocols used by national accrediting organizations, and national consulting firms which have developed quality measurement tools for us in the past.

Comment: One commenter asked if health plans will have to create an entirely different audit response to the protocols in addition to responding to the existing standards of NCQA and of other State entities.

Response: Because the protocols were based on quality assessment approaches already in use by public and private quality oversight organizations, we believe that the methods MCOs and PIHPs use to respond to existing private and public sector audits will be able to be used to respond to EQR. In addition, the nonduplication provisions under § 438.360 are revised in the final rule to allow States in certain circumstances to exempt both Medicare+Choice (M+C) organizations and MCOs and PIHPs meeting standards of national accrediting organizations approved and recognized by CMS for M+C deeming