

protocols specified that, “the protocols must be sensitive to the effect the burden to produce or provide additional data and information will have on organizations’ ability to carry on their day-to-day operations.” We also specified that the protocols incorporate, as much as feasible, the tools, techniques, and methods to assess and improve health care quality already in place in the private sector. As a result, we believe the protocols impose the minimal additional burden necessary to carry out the statutory requirement.

*Comment:* In order to allow for parents to choose an MCO for their child on the basis of pediatric care, one commenter stated that the protocols should require that data on pediatric populations be analyzed apart from data on the MCO’s adult population. The commenter also suggested that pediatricians and pediatric subspecialists have input into the development of the protocols.

*Response:* As required by statute, the protocols were developed by an independent quality review organization. In the scope of work for that contract, we required that the organization convene a panel composed of (1) current EQRO contractors; (2) CMS representatives; (3) State Medicaid agency directors, (4) managed care directors and quality system managers; (5) State licensure agencies; (6) advocacy groups; (7) health plans; (8) accrediting agencies; and (9) other experts in the area of quality improvement. A number of these panel members had experience with child health issues. We published a notice in the **Federal Register** on November 23, 2001 announcing the completion of the protocols and asking for comment on their burden. At the same time, the protocols were also made available on our website. The protocols are a methodologically sound set of generic instructions that will guide the reviewer in assessing quality. These instructions can be used for the entire Medicaid population in the MCO or PIHP or, in some instances, can be used for subpopulations such as children who receive Medicaid services. Some protocols address how MCOs, PIHPs, and States can stratify by specific populations, such as older adults or children with special health care needs. In addition, we note that States currently use many performance measures related to care for children. We, therefore, do not believe it necessary for the protocols to address pediatric populations apart from adult populations.

*Comment:* One commenter asked that we provide a definition for and

examples of performance measures and performance improvement projects. One commenter agreed that we should not include the protocols in the proposed rule, given the dynamic state of quality evaluation and measurement. The commenter asked that we clarify what protocols for “calculating performance measures” means, that is to clarify whether it refers to protocols for the development of measures, the calculation of performance thresholds from reported measures, or some other EQR function.

*Response:* The definition and explanations of performance measurement and performance improvement projects are discussed in both the Medicaid managed care final rule and, in detail, in the protocols for calculating performance measures, validating performance measures, conducting performance improvement projects and validating performance improvement projects. In general, we refer to performance measurement as the calculation of the rate at which a desired event occurs. Readers are referred to the protocols available at <http://www.cms.hhs.gov/medicaid/managedcare/mceqrhmp.asp> for further discussion.

*Comment:* Many commenters believed that the protocols should require MCOs to report on Americans with Disabilities Act (ADA) compliance issues for themselves and their providers to ensure that persons with disabilities have an opportunity to benefit from covered services that is equal to persons without disabilities.

*Response:* Compliance with the ADA provisions is addressed in the Medicaid managed care final rule and in the EQR protocol entitled Monitoring Medicaid Managed Care Organizations (MCOs) and Prepaid Inpatient Health Plans (PIHPs)—a protocol for determining compliance with the Medicaid managed care final rule provisions. It is the State’s responsibility to ensure that its MCOs and PIHPs comply with Federal laws, including ADA.

*Comment:* Many commenters recommended that the sample for calculating performance measures, including baseline and follow-up measures for performance improvement projects, should be sufficient to look at specific measures of clinical care; and that the protocols should describe how reviewers will analyze the quality of care when data are missing. The commenters also believed that the protocols should require that MCOs use a common core of widely used, objective performance measures that are issued annually and revised as needed to reflect advances in performance

measurement, that these measures and their methods of calculation be publicly available, and that they include measures for persons with special health care needs. The commenters also recommended that MCOs be required to (1) collect specified HEDIS measures; (2) conduct the Consumer Assessment of Health Plan Study (CAHPS) survey; and (3) conduct a focus study annually of specialized services to persons with special health care needs. The EQR should evaluate these measures in making findings on the quality of care. Finally, the commenters asked that instructions be provided on how to adapt the measures to FFS and PCCM settings and for those enrolled less than 12 months.

*Response:* As stated before, the protocols are a set of methodologically sound generic instructions that will guide a reviewer in assessing quality. The protocols include instructions on proper sampling methodology, assessing missing data, and processes for analyzing data. The protocols do not specify which performance measures are to be used. Performance measures are chosen by the State or MCO or PIHP and will vary over time. The Medicaid managed care final rule gives us the authority to require specific performance measures and levels if we decide to do so in the future. The results of the EQR, however, will be made available to the public upon request and will identify the specific measures collected, the technical methods of data collection and analysis, and the conclusions drawn from the data.

The BBA placed the requirement for EQR on capitated managed care programs, but not on FFS or PCCM settings. Therefore, we do not in this rule provide an explanation of how to adapt these activities to the FFS/PCCM environment. We do, however, encourage States to address the quality of care provided in these service delivery systems. Through a new partnership initiative with State Medicaid and State Children’s Health Insurance Programs (SCHIP), we will be discussing how best to apply performance measures to these two delivery systems.

*Comment:* One commenter asked that we retain the ability of State agencies to continue to improve the protocols as advancement occurs in the art and science of quality measurement. Several commenters stated that because the protocols may quickly become out of date because the field of quality improvement is constantly changing, they should not be promulgated as regulation. These commenters were concerned about CMS developing