

business of accreditation. The commenter believes this bias limits flexibility in the process and promotes a narrow view of performance measurement and jeopardizes State's ability to be innovative in performance measurement.

*Response:* One reason we did not include the protocols in a regulation was because we recognize that the protocols will need to be updated as the state-of-the-art in quality assessment and improvement changes. However, we believe that the activities listed in the protocol are still those in current use in the industry. Further, to be in compliance with the EQR rule, States only need to ensure that our protocols or those consistent with ours are used.

In addition, we do not agree that the protocol is biased toward proprietary systems. We used three sources to develop the performance measures protocols (that is, NCQA's HEDIS validation protocol, IPRO documents, and documents from the MEDSTAT group). We identified activities common to these tools and incorporated those activities to ensure valid and reliable methods are used when calculating or validating performance measures. Only one of these tools was developed by an organization that is in the business of accreditation, and we do not agree that the performance measures protocol limits State flexibility in the performance measures development process. We provide States with the flexibility to use established measures or to develop their own measures. We recommend, however, when States choose to develop or use measures not widely used in the private and public sector, that these measures should be evidenced-based and tested.

*Comment:* Several commenters believe the process described for validating performance measures is bureaucratic and administratively burdensome. The commenters state that they do not understand the value of interviewing MCO staff and believe annual onsite review is not necessary and is burdensome.

*Response:* The process in the protocols for validating performance measures is consistent with the process used in the private sector and the Medicare program. We drew from established tools in the development of these protocols. The protocol includes interviewing MCO and PIHP staff in addition to reviewing MCO/PIHP documentation of how performance measures are produced. The purpose of interviewing staff is not to obtain information that can otherwise be obtained from documentation. It is to supplement and confirm information as

needed. In the protocol, interviews of MCO/PIHP personnel are identified as an effective mechanism to understanding an MCO's/PIHP's IS and its application to performance measurement. While much information can be obtained by reviewing an MCO's/PIHPs internal documents describing its IS, we believe that interviews with MCO/PIHP staff can be a helpful adjunct to the review of IS documents in understanding the issues the MCO/PIHP has with respect to ISs and how it affects the MCO's/PIHP's production of performance measures.

*Comment:* One commenter argued that some States calculate and report MCO-level performance measures and therefore, much of what is contained in the calculating performance measures protocol is not applicable to MCOs, but is applicable to the State.

*Response:* We recognize that States may have MCOs and PIHPs submit encounter data to them instead of performance measures and, therefore, the State may be the entity calculating the performance measure. We have allowed for this in the quality assessment and performance improvement program requirements specified in § 438.240 of the Medicaid managed care final rule. However, regardless of who calculates the performance measures, MCO and PIHP-level performance measures must be calculated as required by the Medicaid managed care final rule and, if calculated by the MCO/PIHP, must be validated to provide information for the EQR function. We have added clarifying language under § 438.358(b)(2) to recognize that States may be calculating the MCO/PIHP performance measures and in this circumstance the State would provide the information obtained from this activity to the EQRO for the EQR function.

*Comment:* One commenter suggested combining the validating performance measures protocol and the calculating performance measures protocol to reduce the length and complexity of the two protocols.

*Response:* We purposefully provided separate protocols for each EQR-related activity. Even though some of the protocols are variations on a theme (for example, validating performance measures and calculating measures) we wanted to provide stand-alone documents for each activity. In addition, though the protocols are variations on a theme, the activities do differ somewhat and we believe the clearest way to present the information is in separate documents.

*Comment:* One commenter argued that the 30 sample medical record

review recommended in the protocol for performance measures not calculated with administrative data only will add tremendous cost, is needlessly intrusive, and is very time consuming.

*Response:* This aspect of the protocol illustrates what we mean when we say that States must use protocols that are consistent with (but not identical to) our protocols. In this protocol, onsite Activity 4 is the "Assessment of Processes to Produce Numerators." To be consistent with our protocol, the EQRO must perform this activity (that is, assess the MCOs' or PIHPs' processes to produce the performance measure numerator). In our description of Activity 4, we describe how this activity is to be conducted and state that this activity should include a review of a sample of the medical records used to determine the numerator. Thirty medical records is the number that was included in the private sector protocols we reviewed. However, EQROs may use another sample size and still be consistent with our protocol. Our protocol endorses the policies found in private sector protocols, that require a sufficient number of medical records be reviewed to validate a reported numerator for a given performance measure. As stated previously, however, activities used to provide information for the EQR must be conducted "consistent with" our protocols. "Consistent with" means that the protocols used contain all of the activities and steps included in our protocols. How EQROs and States implement the activities and steps is left to their discretion.

*Comment:* One commenter suggested we add lab data as a data source to calculating performance measures numerators (page 8, item 4).

*Response:* We agree with the commenter and have added laboratory data as a possible data source for calculating performance measures.

*Comment:* One commenter suggested some editorial changes.

*Response:* We have made editorial changes that were recommended where we thought appropriate and helpful.

*Comment:* One commenter suggested on page 15 we add "place of service" to the list of claims and encounter data elements to be assessed when assessing the integrity of the MCO's/PIHP's IS.

*Response:* We agree with the commenter and have added place of service to the list of claims and encounter data elements that may be used to conduct performance measurement.