

D. Quality Assessment and Performance Improvement (Subpart D)**Background**

Section 4705 of the BBA added section 1932(c) to the Act. Section 1932(c)(1) requires State agencies that contract with Medicaid MCOs under section 1903(m) of the Act to develop and implement quality assessment and improvement strategies that are consistent with standards established by the Secretary. Subpart D would implement this provision. We proposed that the requirements be applied to PIHPs and, in some cases, to PAHPs.

1. Scope (Proposed §438.200)

Proposed §438.200 set forth the scope of subpart D. Proposed subpart D would implement section 1932(c)(1) by setting forth specifications for quality assessment and performance improvement strategies that States must implement. Subpart D also proposed standards that would apply to States, MCOs, Prepaid Inpatient Health Plans (PIHPs), and in some cases, Prepaid Ambulatory Health Plans (PAHPs).

Comment: One commenter stated that the provisions of subpart D were appropriate overall but that more flexibility is needed for smaller States and MCOs because their administrative burden is greater. Many commenters supported the approach taken in the August 2001 proposed rule and the balance struck between requirements and flexibility. They stated their belief that subpart D avoids the imposition of requirements with administrative burden and serves the interest of beneficiaries.

Response: We believe that §438.204 provides the structure for State quality strategies consistent with the intent of the Congress when it addressed quality in section

4705(a) of the BBA. We also believe that we have provided sufficient flexibility for States to design and implement quality strategies that will best meet their needs. We do not relax the requirements for smaller States or MCOs because we do not believe that quality should be compromised due to the size of an organization. However, we do not believe the burden on States is excessive, even for smaller States, and we believe that States may impose the appropriate activities on MCOs and PIHPs. For example, a State might require less in the way of quality assessment and performance improvement activities for smaller plans. The State also might contract with an organization that does external quality review for the State pursuant to section 1932(c)(2) of the Act, to calculate performance measures or design quality improvement projects. (See 64 FR 67223, December 1, 1999 for the proposed rules that would govern “External Quality Review Organizations,” or “EQROs.”)

Comment: Many commenters stated that the provisions of subpart D should apply to PAHPs, including dental plans, as well as to MCOs and PIHPs. They believe that all capitated programs, including those that provide transportation, should be subject to the quality provisions. Other commenters stated that exempting “mental health carve out” plans from the quality requirements is inconsistent with the findings of the General Accounting Office (GAO) report of September, 1999 on mental health carve out programs in Medicaid managed care.

Response: We agree with the commenter. Therefore, in this final rule, we have applied additional sections of the regulation to PAHPs. (See §438.8(b).) In subpart D, we now apply the provisions of §§438.206, 438.207, 438.208, 438.210, 438.214, 438.230, and 438.236 to PAHPs. These sections address access to care and the provision of quality

care. We believe that the protections of these sections should be extended to enrollees in PAHPs. We do not apply the other provisions of subpart D related to a quality strategy and quality improvement activities, as we believe these requirements would impose a burden on States and PAHPs that is unreasonable given the scope of PAHP activities.

The terms “mental health carve out program” or “behavioral health carve out program” refer to prepaid plans that provide only mental health services. Under a waiver, a State Medicaid managed care program can contract with such a program. The GAO Report issued on September 17, 1999, indicated that CMS needs to oversee mental health carveouts more systematically, and noted approvingly that we were developing a rule that would include a requirement for annual external quality reviews. Mental health carve out programs that provide hospital as well as ambulatory care are PIHPs, and are subject to all the subpart D requirements. We believe that most of the large mental health carve out programs fall into this category, and that this final rule is therefore consistent with the intent of the September 1999 GAO report.

2. State Responsibilities (Proposed §438.202)

Proposed § 438.202 set forth the State’s responsibilities in implementing its quality strategy. Specifically, proposed §438.202 required that each State (1) have a written strategy for assessing and improving the quality of managed care services, (2) provide input by stakeholders into the strategy, (3) ensure compliance with State-established standards, (4) periodically review the strategy for its effectiveness and update as needed, and (5) submit to CMS a copy of the initial and revised strategies and regular reports on their implementation and effectiveness.

Comment: One commenter suggested that in §438.202 “strategy” be replaced with “policy.”

Response: Section 1932(c)(1) of the Act requires a State to develop and implement a quality assessment and improvement strategy if it contracts with an MCO. Therefore, we retain the term “strategy” in §438.202 of the final rule to be consistent with the term used in the statute.

Comment: One commenter believes that the provisions regarding a State quality strategy are heavy handed, over controlling, and result in CMS substituting its judgment regarding quality for the State’s.

Response: We believe the regulation provides a balance between an appropriate amount of detail needed to ensure that States develop and implement sound quality strategies and flexibility for States to determine the best approach for developing these strategies.

Comment: One commenter said that the State’s quality strategy should clearly outline the relationship between the MCO and PIHP quality requirements and the strategy components. Each MCO and PIHP requirement should clearly support a component of the strategy.

Response: The MCO and PIHP quality requirements of subpart D (§§438.206 through 438.242) are incorporated as an element of the State’s quality strategy (§438.204(g)). Specifically, §438.204(g) requires that the State quality strategy include information on how the State plans to make MCOs and PIHPs comply with State access standards, structural and operational standards, and measurement and improvement

standards. We do not believe we need to revise §438.204 to provide clarifying language to show the relationship between the quality strategy and the MCO and PIHP quality requirements under §438.240.

Comment: Many commenters stated that the requirement in proposed §438.208(c) and (d) (now §438.208 (b) and (c)) for States to assess the quality and appropriateness of care and services furnished to all Medicaid enrollees, including those with special health care needs, is ambiguous. Commenters believe it can be read to mean that the overall population must be measured, including special needs populations, rather than that the quality for special needs populations be measured separately. They see this as a problem because the results may yield no specific information about persons with special health care needs.

Response: Our intent for the proposed provision was to have States assess the quality and appropriateness of care and services to all Medicaid enrollees as well as to assess separately the quality and appropriateness of care and services for individuals with special health care needs. For clarification purposes, we have revised §438.208(b) and (c).

Comment: One commenter objected to the inclusion of the word “all” in §438.204(b) because States do not have the budgets or staffs to assess the needs of all Medicaid enrollees.

Response: Section 438.204(b) requires the State to identify in the quality strategy how it plans to implement procedures to assess the quality and appropriateness of care and services furnished to all Medicaid beneficiaries. We disagree with the commenter because

States have the flexibility to determine the methods and timeframes that will work best to assess the quality and appropriateness of care and services to all Medicaid beneficiaries. There are a variety of options States can choose from to meet this requirement. For example, States can use findings from performance measures collected, performance improvement projects conducted, reviews for compliance with State standards, consumer surveys, or the analysis of grievance and appeal information. States can conduct these activities, use a State contractor to conduct these activities, and/or use findings from MCO and PIHP quality assessment and performance improvement programs.

Comment: One commenter questioned if there are specific quality measures for individuals with special health care needs, other than surveys, that can be used to meet the requirement of the regulation that States assess the appropriateness of care of these enrollees.

Response: As stated above, there are numerous activities that can be conducted to assess the appropriateness and quality of care and services provided to beneficiaries. When targeting an assessment of individuals with special health care needs States can stratify the data by identified categories or conduct activities specifically targeted to a specified population. For example, a State could conduct or have their MCOs and PIHPs conduct a performance improvement project on access to care for individuals needing substance abuse services.

Comment: Many commenters suggested that proposed §438.208(b) (now §438.208(c)) should require States to provide information to MCOs and PHPs about Medicaid enrollees known by the agency to have special needs, as this step is crucial to

assessing the quality and appropriateness of care provided to these beneficiaries.

Response: We agree with the commenters. Therefore, we have revised §438.208(c) to require that States implement mechanisms that identify individuals with special health care needs. The State or its enrollment broker may determine which individuals have special needs, and then inform the MCO, or the State may require that the MCO, PIHP, or PAHP apply the mechanisms to identify these individuals.

Comment: Many commenters expressed support for the requirement that State quality strategies be in writing. One commenter mistakenly believed that the proposed rule did not include the requirement that the strategy be in writing and asked that this requirement be included.

Response: We agree with the commenters and we will retain the requirements in §438.202(a). We believe it important that the quality strategy be in writing to provide a document for stakeholders to react to, as well as, for the States to assess on a regular basis and update as necessary.

Comment: Several commenters stated that the regulation appears to contemplate a formal solicitation of public input to the quality strategy. A formal public process is costly and administratively burdensome. One commenter said that they have found a public process to solicit input ineffective. The commenter asked that we clarify in text or preamble language that a less formal process is permissible. Another urged its deletion. Several commenters supported the requirement for public input into the State quality strategy.

Response: Our intent is that there be a formal process to obtain input from beneficiaries and other program stakeholders in the development of the State quality

strategy. We leave it to the State to define this process. We believe public input provides for the integration of various perspectives and priorities and will facilitate a more useful end product. Therefore, we retain the requirement in §438.202(b) of this final rule.

Comment: One commenter expressed concern that the regulation will require a continual process of formal comments on a State's quality strategy because it will change frequently as new quality tools become available, laws and regulations change, and CMS places conditions on States when approving waivers.

Response: As stated above, we intend for States to obtain public comments on updated quality strategies when significant changes are made. We do not expect States to obtain public comments when modifications are made to the strategy that are not considered significant, as defined by the State.

Comment: Many commenters believe that CMS should specify a timeframe for States to update their quality strategies, such as annually or every 3 years. They believe that "periodic" is insufficient, as the term is not defined. One commenter stated that the review should be conducted annually, the review should identify the degree to which the MCO or PIHP interventions continue to support the goals of the strategy, and the findings should be reported annually to CMS and to the public.

Response: We do not agree that we should require a specific time period for States to update their quality strategies. We have provided States with the flexibility to determine these timeframes. We believe that a State's review and evaluation of the effectiveness of the strategy will guide the State's decision as to when and how the strategy should be revised. Therefore, we retain the requirement in §438.202(d).

Comment: One commenter said that the requirement that States submit their quality

strategies to CMS implied a role for CMS in approving the strategy. Another commenter requested a provision stating that CMS' review will be limited to verification that each required element is addressed.

Response: As part of the CMS regional office review of Medicaid managed care programs, regional office staff will assess State quality strategies to ensure compliance with this rule. We have not yet determined the scope of review activities that regional office staff will undertake. As we develop this process, we will work in collaboration with States and other stakeholders.

Comment: One commenter suggested that a provision be included to require States to review health plans' quality strategies at least every 3 years.

Response: MCOs and PIHPs are not required to develop quality strategies. MCOs and PIHPs are required to have a quality assessment and performance improvement program as specified under §438.240. The State is required to review this program annually to determine the impact and effectiveness of the program.

Comment: One commenter stated that progress toward goals in the quality strategy should be shared by States with their MCOs and PIHPs to reinforce collaboration, monitor progress, and make needed revisions.

Response: We encourage States to share findings of the effectiveness of the State quality strategy with MCOs and PIHPs. We are not requiring this, however, in regulation.

3. Elements of State Quality Strategies (Proposed §438.204)

Proposed §438.204 set forth the elements of a State quality strategy, including, in §438.204(a), contract provisions that incorporate the standards specified in this subpart.

Section 438.204(b) required that the State strategy must include procedures that (1) assess the quality and appropriateness of care and services furnished to all Medicaid enrollees, including those enrollees with special health needs; (2) identify and provide to MCOs and PIHPs information on the race, ethnicity, and primary language spoken of each Medicaid enrollee; and (3) monitor and evaluate the compliance of MCOs and PIHPs with these standards.

Section 438.204(c) provided that the State quality strategy must include any performance measures and levels developed by CMS in consultation with States and other stakeholders. “Performance measures” or “measures” refer to how often a desired action or result is achieved or produced, such as the percent of two-year olds who are immunized. “Levels” refers to a specified percentage to be achieved or a measure.

Section 438.204(d) required an annual, external independent review of the quality outcomes and timeliness of, and access to, the services covered by the MCO or PIHP contract.

Section 438.204(e), (f), and (g) required that State strategies use intermediate sanctions; include an information system to support the operation and review of the strategy; and include standards for access to care, structure and operations, and quality measurement and improvement, all consistent with the requirements of other sections of this subpart.

Comment: One commenter suggested that States be required to use the definition of children with special health care needs established by the Bureau of Maternal and Child Health and, through monitoring the use of services, identify children who received subspecialty care.

Response: There are numerous definitions for individuals with special health care needs. However, health services research is still in the process of developing conceptual models, screening tools, and approaches to identifying these individuals. We, therefore, do not agree that this regulation should require States to use a particular definition. We provide States with the flexibility to define individuals with special health care needs. This regulation requires that States identify procedures to assess the quality and appropriateness of care provided to individuals with special health care needs and that States conduct reviews to evaluate the effectiveness of the strategy, including quality activities targeting individuals with special health care needs.

Comment: Many commenters strongly supported the provision that States be required to identify the race, ethnicity, and primary language spoken of each Medicaid enrollee and provide this to the MCO or PIHP upon enrollment. This supports the HHS goal of eradicating racial and ethnic disparities in health care by the year 2010. It also ensures that MCOs and PIHPs have the information necessary to comply with title VI of the Civil Rights Act of 1964. They allege that it has been long recognized that effective recording and reporting of data is the basis used to determine that Federal fund recipients are in compliance with the law.

Response: To ensure that Medicaid services are provided in a manner that meets the needs of beneficiaries, we retain the provision in §438.204(b)(2) in the final rule.

Comment: One commenter urged that the regulation permit the collection of information on race, ethnicity, and primary language at both the State and MCO and PIHP level. They note that State data is not always accurate.

Response: In addition to the information provided to MCOs and PIHPs by the

States, MCOs and PIHPs have the option to collect information on race, ethnicity and primary language. We are not requiring this in regulation but we note that States may do so.

Comment: One commenter asked for clarification on the level of specificity that would be required to meet the requirement to collect data on ethnicity.

Response: We are providing States with the flexibility to determine how they would like to define and categorize ethnicity. Ethnicity information is collected for census purposes and we encourage States to consider using standard categories used by the Bureau of the Census.

Comment: One commenter noted that race data in State eligibility systems is not always accurate and that identifying primary language will cost money to make required systems changes.

Response: We recognize that some States will need to modify their Medicaid Management Information Systems (MMIS) to collect data on primary language. We will allow States sufficient time to modify their systems to capture these data. We also recognize that the race data collected by States may not always be accurate and that it will always be subject to omission due to a variety of factors including beneficiary unwillingness to provide the information.

Comment: One commenter said that information on race, ethnicity, and primary language is not available from the Social Security Administration (SSA) for Supplemental Security Income (SSI) beneficiaries or that States do not control what information SSA collects. States should not be required to provide this information to MCOs unless it is available from SSA.

Response: Information on race is available from SSA on SSI beneficiaries and is available to States through the State Data Exchange (SDX) file. Information on ethnicity and primary language, however, is not available from SSA. We encourage States to pursue methods to collect information on ethnicity and primary language spoken for these beneficiaries. The information may be available in files of other State programs. We recognize that this information may not be complete for a variety of reasons.

Comment: One commenter said that the State has no legitimate interest in the primary language spoken by beneficiaries, as this does not indicate that use of English presents a barrier.

Response: We disagree with the commenter. We believe that the primary language spoken by a beneficiary indicates that there could be a potential barrier to appropriate use of health care services.

Comment: Several commenters said that data on race, ethnicity, and primary language are difficult to collect and unreliable due to the reliance on self-reporting. One commenter noted that undocumented parents may be reluctant to apply for benefits if this question is asked. The commenter further suggested that this provision be deleted or not required.

Response: Self-report data are used for numerous purposes including consumer satisfaction surveys and initial screening of beneficiary needs. There are methodological pros and cons to using any types of data, including self-report data. While we realize that self-report data about race, ethnicity, and language will not always be completely reliable, we believe that collecting it will allow MCOs, PIHPs, and PAHPs to take into account the cultural barriers that may undermine the delivery of health care to particular populations

enrolled in the MCO. We do not believe that collection of this information will discourage undocumented parents from applying for benefits for eligible children because the question will be in reference to the children.

Comment: One commenter said that requiring beneficiaries to disclose race or ethnicity constitutes a potential violation of the Civil Rights Act.

Response: This rule does not require beneficiaries to disclose race or ethnicity. It requires States to make an effort to identify this information. In addition, the Civil Rights Act of 1964 does not prohibit a State or any other Federally assisted entity from asking a beneficiary to disclose his or her race or ethnicity. The failure to disclose the requested information, however, cannot be used as a basis to deny services or benefits to the beneficiary.

Comment: Several commenters noted that the requirement for States to collect information on race, ethnicity, and primary language would require systems modifications and training of intake staff. The commenter expressed the hope that CMS, when conducting compliance reviews, would be sensitive to the time it will take for States to fully implement this provision. Another commenter suggested that States may need technical assistance.

Response: We recognize that some States will need to modify their MMIS systems to capture these data, although we believe most States are already capturing data on race and ethnicity. We will allow States sufficient time to modify their systems to capture these data. We also recognize that training of intake staff may need to occur and that technical assistance to State may need to be provided. We plan to conduct training pertaining to the implementation of the provisions in this rule shortly after its publication. Comment:

One commenter suggested that the regulation require States to furnish MCOs and PIHPs with the age of children being enrolled along with information on race, ethnicity, and primary language spoken.

Response: The purpose of requiring States to identify race, ethnicity, and primary language is to facilitate the appropriate delivery of health care services. We believe that MCOs and PIHPs can adequately obtain age information from the enrollee and are, therefore, not requiring that the age of enrolled children be provided.

Comment: One commenter appreciated that we are permitting States to develop strategies for identifying race, ethnicity, and primary language, rather than requiring States to identify these factors.

Response: We believe the commenter misunderstood the provision. The regulation requires States to identify the race, ethnicity, and primary language of enrollees.

Comment: One commenter asked that States be required to provide the date of redetermination for new enrollees to MCOs and PIHPs. This would allow MCOs and PIHPs to outreach to enrollees to ensure that eligible beneficiaries continue to receive services.

Response: We do not agree that this regulation should require States to provide the date of redetermination for new enrollees to MCOs and PIHPs. If MCOs and PIHPs would find this information useful to provide continuity of services and do not currently receive it, we suggest that they raise this issue with their State.

Comment: One commenter asked that the requirement in proposed §438.204(b)(3) for “continuous” monitoring be changed to “periodic” monitoring as continuous means nonstop, and this is an unreasonable requirement.

Response: We agree with the commenter and have revised §438.204(b)(3) of the regulation text to provide for regular monitoring, as opposed to continuous monitoring.

Comment: Many commenters applauded the provision that performance measures and levels be identified and developed by CMS in consultation with States and other stakeholders. Some recommended that beneficiaries and groups that represent them should be among the stakeholders consulted. One commenter suggested that CMS ask the American Association of Health Plans (AAHP) to obtain recommendations and comments about proposed measures from MCOs. Others urged that performance measures be implemented in a way that allows MCOs to meet a realistic schedule. They further recommended that CMS take into consideration nationally demonstrated performance levels in both MCOs and in State fee-for-service (FFS) programs. One commenter recommended that any new measures be tested for one year to assess the data and results before States, MCOs and PIHPs are considered out of compliance.

Response: We anticipate that States, beneficiary advocacy groups, and MCOs and PIHPs would all be invited by CMS to participate in the process to develop standard measures. The implementation process would be discussed at this time and would include issues such as measure specifications, testing of measures, and measure reporting. States would need to ensure that their contracting MCOs and PIHPs collect any measures specified by CMS. We would encourage States to also use standard measures in their FFS programs. If CMS prescribes any national performance measures, it will consider a testing phase. Finally, should CMS consider setting levels for performance measures, we would consider levels used in both managed care and FFS programs

Comment: One commenter suggested that the number of national measures be

limited so as not to unnecessarily increase costs or burden or interfere with State efforts.

Response: We agree that national measures should be limited in number.

Comment: One commenter suggested that quality improvement initiatives must be recognized as long-term efforts and that States and MCOs must partner to identify meaningful topics that should be measured, and track these over time. Continual, capricious changes to quality initiatives are not conducive to meaningful study and improvement.

Response: We agree with the commenter and acknowledge that a quality improvement initiative (the process of measuring performance, implementing interventions to respond to identified quality problems, and then remeasuring performance) needs sufficient time to be implemented and for findings to be made available. We do not prescribe the duration in which performance improvement projects must be completed. We expect States to require that a project be completed in a reasonable time period and that information be provided on the project's progress annually.

Comment: One commenter requested detailed standards to ensure that Medicaid children are receiving the care to which they are entitled. Specifically, the commenter recommended the regulation include standards for accreditation of MCOs and PIHPs, consumer satisfaction and quality of care "report cards," and use of criteria consistent with national standards for assessing outcomes of care of children. In addition, the commenter suggested that CMS work with states to develop criteria and a timetable for improving the reporting of early and periodic, screening, diagnosis and treatment (EPSDT) services.

Response: The provisions under subpart D provide for access standards, structural and operational standards, and measurement and improvement standards. These standards

apply regardless of the composition of the Medicaid population that is provided health care services through a State Medicaid managed care program. A review of these standards will be conducted as specified in the forthcoming final External Quality Review (EQR) regulation (64 FR 67223). As part of EQR, we have proposed that States may contract with external quality review organizations (EQROs) to conduct consumer surveys and validate and calculate performance measures and obtain a 75 percent enhanced Federal matching rate. Alternatively, States can have a contractor that is not an EQRO conduct these activities, and obtain the 50 percent administrative matching rate. States, the EQROs they contract with, or other State contractors will be able to extract information obtained from these quality measurement activities in a way that allows them to look at the quality of care of specified populations, including children. Regarding the comment about EPSDT, we do not believe that this is within the scope of this regulation.

Comment: Many commenters suggested that only non-medical PHPs (that is, transportation and dental) be excluded from the requirement for EQR and that a State audit substitute for the EQR for these entities.

Response: We have proposed to exclude all PAHPs, including transportation and dental PAHPs, from the EQR requirements. We believe that requiring EQR for PAHPs would impose an unreasonable burden given the limited scope of their services.

Comment: One commenter stated that many States conduct extensive quality reviews, either through another State agency or through an accreditation organization. These reviews, the commenter contended, are similar to or more rigorous than the CMS required external review and he suggested that, if a review is done by another State agency or an accreditation organization, that the MCO or PIHP be exempt from the EQR.

Response: We plan to address when an MCO or PIHP can be exempt from certain EQR activities or from EQR in its entirety in the final EQR regulation.

Comment: One commenter asked if it will be permissible to contract with State medical and allied health professional schools for EQR.

Response: We plan to address who is qualified to be an EQRO in the final EQR regulation.

Comment: One commenter mistakenly believed that we deleted the EQR requirement from the quality strategy and was in agreement with this deletion arguing that the requirement was excessive and costly.

Response: Section 1932(c)(2) of the Act requires an EQR of managed care activities. While we have included the EQR requirement as part of the quality strategy under this subpart, specific requirements regarding compliance with the EQR provision were published in a separate EQR Notice of Proposed Rulemaking on December 1, 1999 (64 FR 67223). The final EQR rule is forthcoming.

Comment: One commenter stated that some PIHPs have enrollments of less than 200 and serve fewer than 10 beneficiaries a year. The commenter is concerned that for these PIHPs the cost of an EQR could exceed the costs of providing health care services. The commenter suggested that for PIHPs include an option for Section 1115 and 1915(b) waiver programs allowing the use of the independent assessment of the waiver program in lieu of an EQR.

Response: The independent assessment requirement only applies to programs operated under section 1915(b) waivers, and if the assessment is found to be acceptable, is generally required for only the first two waiver periods. It does not apply to a managed

care program conducted under section 1932(a) or section 1115 of the Act or one that enrolls beneficiaries in managed care on a voluntary basis. We therefore do not agree that this option is a suitable replacement for the EQR requirement. If a PIHP contracts with a State to provide services to Medicaid beneficiaries it will be required to comply with the provisions in this rule including the EQR requirements.

Comment: One commenter recommended that §438.204(e), which requires the use of intermediate sanctions, be amended to indicate that it is applicable to MCOs only and not to PIHPs because subpart I does not apply to PIHPs.

Response: We agree with the commenter and have deleted the reference to PIHPs under §438.204(e). In addition, to clarify the applicability of §438.204(c), we have included language that clarifies that this provision applies to both MCOs and PIHPs.

4. Availability of Services (Proposed §438.206)

Section 1932(c)(1)(A)(i) of the Act, as added by section 4705 of the BBA, requires each State that contracts with MCOs under section 1903(m) of the Act to develop and implement standards for access to care under its quality assessment and improvement strategy. Section 438.206 of the proposed rule established standards for access to care. Paragraph (a) required that States ensure that all covered services are available and accessible to enrollees. Paragraph (b) proposed new requirements for the delivery networks of MCOs and PIHPs. These requirements would be imposed on State agencies, which in turn would enforce these requirements on MCOs and PIHPs through contract provisions.

Specifically, paragraph (b)(1) proposed that all MCOs and PIHPs maintain and monitor a network of appropriate providers that is supported by written arrangements and

is sufficient to provide adequate access to covered services. In establishing and maintaining such a network, the proposed rule required MCOs and PIHPs to consider (1) anticipated enrollment; (2) the expected utilization of services, considering enrollee characteristics and health care needs; (3) the numbers and types of network providers required to furnish contract services; (4) the number of network providers who are not accepting new patients; and (5) the geographic location of providers and enrollees, considering distance, travel time, the means of transportation normally used by enrollees, and whether the location provides physical access for enrollees with disabilities.

In §438.206(b)(2) we proposed that the State be required to ensure that MCOs and PIHPs allow women direct access to a woman's health specialist for women's routine and preventative services. Proposed §438.206 (b)(3) required that MCOs and PIHPs provide for a second opinion from a qualified health care professional within the network, or arrange for the enrollee to obtain one outside the network, at no cost to the enrollee. In paragraph (4), we proposed that the MCO or PIHP must cover medically necessary services for enrollees obtained outside the network if, and for as long as, they cannot be obtained from within the network. Paragraph (5) of the proposed rule required out-of-network providers to coordinate with the MCO and PIHP with respect to payment and ensure that the cost to the enrollee is no more than it would be if the services were provided within the network. In paragraph (6), we proposed that MCOs and PIHPs demonstrate that their providers are credentialed in accordance with §438.214(b).

Paragraph (c)(1) required MCOs and PIHPs to meet State standards for timely access to services and to require that their providers also meet these standards. It also required MCOs and PIHPs to (1) ensure that network providers offer hours of operation

that are no less than the hours of operation offered to commercial enrollees or comparable Medicaid fee-for-service, if the provider serves only Medicaid enrollees; (2) make services available 24 hours a day, 7 days a week, when medically necessary; (3) establish mechanisms to ensure compliance with these requirements; (4) monitor for compliance continuously; and (5) take corrective action if there is a failure to comply.

Paragraph (c)(2) required that the State ensure that each MCO and PIHP participate in State efforts to promote the delivery of services in a culturally competent manner to all enrollees with limited English proficiency and diverse cultural and ethnic backgrounds.

Comment: Many commenters said that the provisions in proposed §438.206 should apply to all PHPs because PAHPs should have the same requirements for an adequate provider network as applies to MCOs and PIHPs. One commenter said that this section should apply to dental plans.

Response: We agree with the commenters that the availability of services provisions should apply to PAHPs. Therefore, in §438.206 of the final rule, we have added “PAHP” in each instance in which the terms “MCO or PIHP” appeared in the proposed rule. Therefore, these requirements will now apply to dental PAHPs. We note that the types of providers that a PAHP must include in its network is limited to those needed to provide the services under its contract.

Comment: Several commenters supported the provisions at §438.206(a) requiring that all covered services be available and accessible.

Response: We agree with the commenters and believe that these provisions are consistent with the intent of the Congress concerning the development and implementation of standards for access to care.

Comment: Many commenters said that proposed §438.206(b) fails to provide for direct accountability by States in that it provides only that States ensure compliance *through their contracts*. These commenters believe that this wording does not require States to ensure that the contract provisions are carried out in practice.

Response: We agree with the commenter. We now specify in the regulation that §438.206 be reflected in contracts with MCOs, PIHPs, and PAHPs, because it is essential that these requirements be included in the contract to be enforceable by the State. The regulation also requires, at §438.204(b)(3), that States “monitor and evaluate the MCO, PIHP, and PAHP compliance with the standards”.

Comment: One commenter said that a requirement that MCOs have a network “sufficient to provide adequate access to all services under the contract” is a significant departure from 1902(a)(30)(A) of the Act that requires the State to establish methods, procedures, and payments “sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in a geographic area”. The commenter is concerned that the language in the proposed regulation obligates the State to guarantee that all covered services are available at all times, which may be beyond the ability of the State due to shortages of service providers.

Response: Section 1902(a)(30)(A) is a requirement that applies to the State’s fee-for-service program, operated pursuant to the State plan. The provision that specifically governs the availability of services under a State’s managed care program is section 1932(c)(1)(A)(i) of the Act, which requires that services be available “in a manner that ensures continuity of care and adequate primary and specialized services capacity.” We

believe that the provisions of §438.206(b)(1) carry out the intent of the Congress under section 1932 to provide access standards that will ensure the availability of care in MCOs, PIHPs and PAHPs.

Comment: One commenter expressed support for the provision requiring networks to have experienced providers.

Response: We agree that it is important that MCOs, PIHPs, and PAHPs have experienced providers in order to provide quality care to Medicaid enrollees. This is especially true for enrollees with special health care needs, whose needs may be sufficiently rare or complex due to multiple conditions that a provider, even one who is a specialist, may have little or no experience in treating the enrollee's condition or conditions. Accordingly, in section 438.206(b)(1)(iii) we specify that the MCO, PIHP, or PAHP must consider the training, experience, and specialization of providers.

Comment: One commenter recommended adding language to require MCOs and PIHPs that serve children with special health care needs to include appropriately trained physicians in their network, including pediatric specialty and subspecialty physicians.

Response: We do not believe it necessary to include an explicit requirement for specific specialty and subspecialty physicians for particular groups of enrollees. The general requirement that a network be adequate to provide access to all services under the contract, taking into account the anticipated enrollment and the expected utilization, is sufficient to ensure that the network will be adequate to meet all needs. Inclusion of language related to particular groups may even be detrimental in that it would be impossible to list the particular requirements of all groups.

Comment: One commenter suggested that we add an explicit requirement that

MCOs and PHPs pay particular attention to the needs of enrollees with disabilities when developing and maintaining networks. Without such a provision, the commenter is concerned that specialized psychiatric treatment for children and adults with severe mental illness may not be available. The commenter believes that the inclusion of such a requirement has the potential to bring psychiatrists who refuse to treat FFS Medicaid beneficiaries into the program because MCOs would use their market power to recruit these providers.

Response: As stated above, we do not agree that we should address the special needs of particular groups of enrollees for specialty providers. We believe that the requirement of the regulation for adequate provider networks will cause the States to include appropriate requirements in their contracts with MCOs, PIHPs, and PAHPs and that the assurances of adequate capacity and services, provided under §438.207 of this regulation, will further ensure that provider networks include the range of providers necessary to meet the needs of their enrollees.

Comment: Several commenters suggested that the regulation include a provision that MCOs and PIHPs pay particular attention to pregnant women and individuals with special health care needs because MCO and PIHPs may interpret a general requirement to require only an overall survey of enrollees, rather than a targeted assessment of the needs of the most vulnerable and ill patients.

Response: For the reasons stated above, we do not agree that the regulation should include a specific provision for these groups. We believe that the intent of this regulation is clear, that is, that the needs of all enrollees must be met through the provider network.

Comment: One commenter said that the regulation should require States to ensure

that MCOs and PIHPs consider and address existing underutilization problems when establishing and monitoring their service networks.

Response: The regulation places an affirmative obligation on States and MCOs, PIHPs, and PAHPs to consider the needs of their anticipated enrollees and provide an adequate provider network to meet those needs. We believe that this requirement makes it unnecessary to include a provision to address existing underutilization problems.

Comment: Several commenters said that the regulation should require MCOs and PIHPs that seek to expand their service areas to demonstrate that they have sufficient numbers and types of providers to meet the anticipated volume and types of services enrollees in those areas will require. Failure to include this provision could violate sections 1902(a)(19) and 1932(b)(5) of the Act which require State plans to provide safeguards to assure that services be provided, and MCOs to provide assurances that they have the capacity to serve the expected enrollment, respectively.

Response: We do not agree that it is necessary for the regulation to specifically require that MCOs, PIHPs, and PAHPs that seek to expand their service areas have sufficient numbers and types of providers to meet the expected increased enrollee volume. The general requirement that MCOs, PIHPs, and PAHPs have adequate networks applies whatever the service area. Furthermore, §438.207(c) requires that MCOs, PIHPs, and PAHPs submit documentation to the State at any time there has been a significant change in their operation, including changes to the geographic service area.

Comment: Many commenters asked that a provision be included in the regulation to require States to make available all services included in the State plan and make information available to beneficiaries on how to access these benefits. The commenter is

concerned that without this requirement important community services that many State plans include through the Rehabilitation Option, such as services that are part of the assertive community treatment model, will not be accessed by beneficiaries.

Response: States are required to make available to all beneficiaries all services covered in the State plan. States may use voluntary or mandatory managed care to provide some or all of these services. If the beneficiary is enrolled in an MCO that does not provide all Medicaid services, or is enrolled in a PIHP or PAHP (which, by definition, is not a comprehensive risk contract), the State remains responsible for making available all Medicaid services not covered in the contract. The regulation provides that both potential enrollees and current enrollees be informed about the services not covered under the contract and how and where they can be obtained. See §438.10(e)(2)(ii)(E) and (f)(6)(xii).

Comment: Many commenters said that the rule should require States to notify enrollees how and where to obtain services, including transportation, for services covered by the State plan but not included in the MCO, PHP, or PCCM contract.

Response: Section 438.10(f)(6) requires the State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM to notify enrollees annually of their right to request this information. In addition, §438.10(e)(2)(i)(E) requires that this information be provided to potential enrollees at the time the potential enrollee first becomes eligible to enroll in a voluntary program or is first required to enroll in a mandatory program.

Comment: One commenter expressed concern that use of a distance standard for urban enrollees could force travel to outlying suburban areas or neighboring counties. The commenter would like the final rule to include language to protect urban enrollees from

needing to make lengthy trips to obtain services.

Response: The regulation provides that the State must ensure through its contracts that the provider network is accessible to enrollees, taking into account several factors related to geographic location of providers and enrollees. Depending on State and local circumstances, we believe that the significance of the factors listed – distance, travel time, and means of transportation ordinarily used by Medicaid enrollees – will differ. For urban enrollees, States may find that the latter two factors are more important considerations than distance. When using distance for enrollees in urban areas, we believe that States will factor in the other elements and select a distance criterion that meets the overall intent of the regulation. We believe that the State is in the best position to determine how these criteria should be applied in each of its service areas.

Comment: Many commenters applauded the use of the term “women’s health care specialist” because they believe that it recognizes the important role played by a variety of health care professionals in addition to physicians. These commenters asked that “routine and preventative” be defined in order to ensure that MCOs and PIHPs do not place barriers to impede women’s access to women’s health specialists. According to the commenters, the definition should include initial and follow up visits for prenatal care, mammograms, pap tests, family planning, and treatment of vaginal and urinary tract infections and sexually transmitted diseases.

Response: We believe that the use of the words “routine and preventative” in the regulation is sufficient to categorize the types of services that women can access directly through a women’s health specialist.

Comment: One commenter seeks inclusion of a requirement that children have

direct access to pediatricians, including specialists. The commenter noted that the regulation provides for direct access to women's health specialists and that the patient's rights legislation endorsed by the Administration provides for direct access to pediatricians.

Response: We do not believe that it is appropriate to require direct access to pediatricians. While we believe that most children enrolled in Medicaid managed care will have pediatricians as their primary care physicians, pediatricians are not locally available in all areas of the country, and some children will use other physicians, such as family physicians, as their source of primary care. We believe that direct access should generally be to the primary care physician. For women's routine and preventative care we make an exception to this rule because we think it appropriate that women have the choice to see a women's health specialist for routine and preventative care rather than a generalist or other specialty physician.

Comment: One commenter said that the regulation should require direct access to psychiatrists.

Response: We do not agree that the regulation should provide direct access to psychiatrists. We are concerned about coordination of care and believe that States should have the option to require that patients be referred to psychiatrists by their primary care physician. This helps to ensure that the primary care physician is cognizant of both the physical and mental health needs of patients and has the information needed to coordinate the care needed by patients.

Comment: One commenter asked that we retain the provision for out-of-network second opinions from health care professionals, which are not currently available. The

commenter stated that a second opinion for a denied service from an in-network provider is a meaningless right.

Response: We disagree with the commenter. The proposed rule provided for a second opinion from a provider in the network, if one is available, and from a provider outside the network only if there is not another qualified provider within the network. We believe that it is important to provide an enrollee with the right to a second opinion, but we believe that this does not require access to a second opinion from a provider who is out of the network.

Comment: Several commenters believe that second opinions should be given by participating physicians when one in the specialty is available. Enrollees would then only be allowed to go out of network when no qualified alternative exists with the network.

Response: As stated in the previous response, the proposed and final rule provide enrollees the right to a second opinion from a provider within the network if a qualified health care professional within the network is available to provide the second opinion. When a qualified health care professional is not available within the network to give a second opinion, the enrollee may obtain it from a health care professional who is not in the network.

Comment: One commenter suggested that the regulation require that second opinions regarding care for a child be provided by physicians with appropriate pediatric education and training. This would be consistent with the pending patient's bill of rights.

Response: The rule specifies that the health care professional giving the second opinion must be qualified to do so. We leave to the States the responsibility for determining the qualifications to be used. States best know their health care markets and

are responsible for setting provider qualifications and, therefore, are in the best position to make this decision.

Comment: One commenter suggested that the regulation limit second opinions from out-of-State providers to instances in which a qualified professional is not available within the State. In addition, the commenter asked that the regulation require that the nearest out-of-State provider be used.

Response: The regulation provides that second opinions be obtained from a provider in the network if such a qualified provider is available. This limitation applies when the desired out-of-network provider is within or outside of the State. We have not added other requirements to this provision, as recommended by the commenter. This allows States to decide, or to allow MCOs, PIHPs, and PAHPs to decide, who is to provide a second opinion when one is to be obtained from an out-of-network provider.

Comment: One commenter believes that CMS should conduct studies to determine if second opinions routinely result in a change of treatment plan and in better outcomes. Unless it can be established that second opinions result in better outcomes, they do not warrant the extra cost.

Response: We disagree that CMS should study if second opinions result in a change of treatment plan or in better outcomes to document their benefit before establishing them as an enrollee right. Second opinions are widely used and accepted in both FFS and managed care service delivery systems. In FFS, Medicaid beneficiaries can freely access a second opinion by simply seeing another physician. Likewise, in FFS, insurance companies often require confirmatory second opinions before authorizing certain services or procedures. We believe that second opinions are well established in the practice of

medicine in this country and should be available to Medicaid managed care enrollees.

Comment: Two commenters asked that the regulation limit payment to non-participating providers to the Medicaid FFS fee schedule.

Response: We do not require that non-participating providers be paid according to the Medicaid FFS fee schedule. We believe that States are in the best position to determine whether payment limits should apply to out-of-network providers or if the MCO, PIHP, and PAHP should be free to negotiate rates.

Comment: One commenter asked that we retain the requirement that MCO and PIHPs pay for services received out of network when they are not available in the network because this will lead to less disenrollment. Another commenter supported inclusion of this provision.

Response: We agree that it is the responsibility of the MCO, PIHP, or PAHP to pay for services, covered under their contracts, received out of network when they are not available from within the network. The MCO, PIHP, or PAHP must arrange for all services needed by their enrollees. We agree that establishing this as an MCO, PIHP, and PAHP responsibility will decrease enrollee disenrollments. We retain this provision in the final rule.

Comment: Many commenters supported the provision that services received out of network may not result in costs to the enrollee greater than would have been within the network. One commenter asked that the wording be revised so that MCOs and PIHPs would not be responsible for actions by out-of-network providers in relation to fees charged to enrollees.

Response: We believe that it is important that Medicaid enrollees not be placed at

a financial disadvantage should their MCO, PIHP, or PAHP refer them to an out-of-network provider for a covered service because a qualified provider is not available in the network. The MCO, PIHP, or PAHP must negotiate the amount they will pay the provider and, as part of this negotiation, can best ensure that the enrollee does not incur out-of-pocket costs.

Comment: One commenter expressed the opinion that the hours of operation offered commercial enrollees is not relevant to the Medicaid contract. He believes that this requirement is impossible to oversee or enforce and could result in a decrease in the number of providers available to serve Medicaid beneficiaries. Another commenter believes that it is not realistic for Medicaid to achieve this standard because Medicaid reimburses providers significantly less than commercial plans. And another commenter said that it is not usual practice for States to track providers' hours of operation if they do not treat Medicaid patients. One commenter said that the requirement should be that services are available and accessible to the same extent that they are for FFS beneficiaries or the general public. Another commenter supported the provision as written.

Response: In the final rule we have retained the provision related to hours of operation as proposed. The purpose of this requirement is to make certain that Medicaid enrollees have the same access to providers as do enrollees of other payers. We believe that the provision is appropriate and is enforceable by MCOs, PIHPs, and PAHPs through their contracts with providers. Access can be monitored by the State or the MCO, PIHP, or PAHP by reviewing patient appointments or by monitoring enrollee grievances. The commenter who stated that States do not track providers' hours of operation if they do not treat Medicaid patients misunderstood the provision. It applies only to providers in

Medicaid managed care networks. For those providers who serve only Medicaid patients, we set the hours of operation for FFS Medicaid patients as the standard that must also be applied to managed care enrollees.

Comment: One commenter suggested that proposed §438.204(b)(3) should not require States to “continuously” monitor hours of operation, as this represents an increased burden on States. Rather the regulation should require that States monitor for this requirement “regularly”.

Response: We agree that the use of the term “continuously” may be confusing and that “regularly” better conveys our intent. We have revised §438.204(b)(3) of the regulation to reflect this change.

Comment: Many commenters said that the requirement that MCOs participate in States’ efforts to promote the delivery of care in a culturally competent manner is not sufficient. They believe that systems of care must be designed to be respectful of and responsive to cultural and linguistic needs in order to provide equal access to quality health care. Failure to provide information about treatment options in a culturally sensitive way could affect patient compliance, lead to declines in the patient’s health, and escalate costs.

Response: We agree that health care needs to be delivered in a culturally competent manner for it to be most effective. However, in the final regulation we have retained the provision of the proposed rule, that MCOs, PIHPs, and PAHPs participate in State efforts to promote the delivery of care in a culturally competent manner, because we believe that it is through this requirement that MCOs, PIHPs, and PAHP, will gain the knowledge and experience to provide culturally competent care.

Comment: Several commenters supported the approach taken in the NPRM regarding cultural competency and believe that the State is in the best position to lead initiatives on cultural competency. This allows States to advance initiatives crossing FFS and managed care.

Response: We agree with the commenters and have retained this provision in the final rule.

Comment: Many commenters said that MCOs, all PHPs, and PCCMs should be required to provide services in a culturally competent manner because, as recipients of Federal funds, they are all required to do this.

Response: This regulation requires MCO, PIHPs, and PAHPs to participate in State efforts to promote cultural competency in order to comply with the requirements of section 1932 of the Act. It does not address requirements of other statutes that might also apply.

Comment: One commenter objected to the Medicaid rule having what he viewed as weaker requirements relating to cultural competency than the Medicare+Choice rule. He noted that in the preamble to that rule CMS stated that the M+C provisions are consistent with title VI of the Civil Rights Act, recommendations from the President's Race Initiative, and the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

Response: Medicaid is a State/Federal program and States retain responsibility for much of the program and operational policy of their programs. We believe that States can best decide how to advance cultural competency in their managed care programs. We are working with the Medicare program to develop tools for managed care organizations to use

to improve the delivery of culturally competent health care. When these tools are available, we will share them with States so that they can use them at their option.

Comment: One commenter suggested that the new standards developed by the Office of Minority Health (National Standards on Culturally and Linguistically Appropriate Services) be referenced as a more detailed document that clarifies the regulatory provision.

Response: We agree that these guidelines are a valuable tool and we encourage States to review them and consider their use.

Comment: Many commenters suggested the addition of a provision to prohibit discrimination by providers toward Medicaid enrollees. One commenter noted that the President's Commission on Consumer Protection and Quality in the Health Care Industry opposed discrimination on the basis of source of payment.

Response: We have decided not to include a provision in the regulation to prohibit providers from discriminating against Medicaid enrollees. We do not believe that this provision is needed in this regulation. States remain responsible for ensuring Medicaid enrollees adequate access to providers and are in the best position to choose the mechanisms they believe will be effective to ensure this result. We also have a provision in the regulation that requires that network providers offer Medicaid enrollees the same hours of operation offered to commercial enrollees. We believe that this requirement will help ensure equal access for Medicaid enrollees to providers.

Comment: Many commenters recommended inclusion of a provision to require States that limit freedom of choice to comply with the requirements of §438.52.

Response: The requirements related to freedom of choice at §438.52 apply in

accordance with the provisions of that section. It is unnecessary to reiterate or cross reference those requirements in this section.

5. Assurances of adequate capacity and services (Proposed §438.207)

Under the authority of section 1932(b)(5) of the Act, proposed §438.207(a) required that the MCO and PIHP provide the State with adequate assurances that the MCO or PIHP has the capacity to serve the expected enrollment in the service area. Proposed §438.207(b) required that documentation submitted to the State must be in a format set by the State and acceptable to CMS and must demonstrate that the MCO or PIHP offers an appropriate range of services, including preventative services, primary care services, and specialty services. The MCO and PIHP was also required to document that it maintains a network of providers sufficient in number, mix, and geographic distribution.

Section §438.207(c) specified when documentation must be provided including (1) at the time the MCO or PIHP enters into a contract with the State, and (2) whenever there has been a significant change in the MCO's or PIHP's operations that would affect adequate capacity and services such as changes in services provided, benefits, geographic service areas, payments, or enrollment of a new population.

Comment: One commenter recommended that this section apply to dental plans.

Response: We agree that it is important for PAHPs, including dental plans, as well as MCOs and PIHPs to have adequate provider networks and to provide the State with assurances as to the adequacy of their networks. Therefore, in the final rule, we extend the provisions of this section to PAHPs. We note that the provider network for PIHPs and PAHPs need only include provider types necessary to provide the services included in

their contracts.

Comment: One commenter stated that MCOs and PIHPs need to contract with the appropriate number and mix of pediatric-trained specialists and tertiary care centers for children in order to ensure that they have adequate capacity to serve their expected enrollment. If a plan fails to contract with an adequate number of these providers, the plan should be required to provide these services out of network at no additional cost.

Response: As we stated earlier in this preamble, we have chosen not to specify types of specialists or other providers that health plans must contract with in order to meet the requirements of the regulation. Rather, in §438.206(b)(1), we retain the general requirement that provider networks must be adequate to provide adequate access to all services covered under the contract. In §438.206(b)(4), we provide that necessary medical services not available within the network, must be covered by the MCO, PIHP, or PAHP out of network.

Comment: One commenter suggested that this provision be revised to require the State to ensure, through its contracts, that MCOs provide a full range of psychiatric services and have a sufficient number of psychiatrists participating in the plan.

Response: As stated above, in the final rule we are not specifying specific provider types needed by MCOs, PIHPs, and PAHPs, but rather providing a general requirement that the networks be sufficient to provide adequate access to covered services to all enrollees.

Comment: One commenter disagreed with CMS' decision to interpret "adequate assurances" to require extensive documentation suggested in the preamble. The commenter believes that extensive and detailed data are often of little use in determining the adequacy

of the provider network and that network deficiencies are often found when an enrollee changes primary care physicians, calls enrollee services, or files a grievance.

Response: We continue to believe that it is necessary and appropriate for the regulation to require that each MCO, PIHP, and PAHP document that it has adequate provider capacity to provide necessary medical services. The heading for section 1932(b)(5) of the Act is “Demonstration of Adequate Capacity and Services.” We believe that the MCO, PIHP or PAHP cannot demonstrate that it has the capacity to serve its expected enrollment without providing documentation. In addition, we require that the State have documentation to support its certification to the Secretary under §438.207(d). This documentation is required prospectively to avoid problems that may otherwise not be detected until an enrollee complains or takes other steps to address a situation caused by the lack of an adequate provider network.

Comment: Many commenters objected to the omission of a provision to require MCOs and PIHPs to have in place policies and procedures to respond to situations in which there is an unanticipated need for providers with particular types of expertise or an unanticipated limitation on the availability of such providers. The commenters believe that such a provision is necessary to meet the statutory requirement for a quality strategy that includes access standards to ensure that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialty care. Another commenter supported the omission of such a provision.

Response: We have not included a provision in the final rule to require MCOs, PIHPs, and PAHPs to have policies and procedures in place to respond to situations in which there is an unanticipated need for providers or a limitation on the availability of

needed providers. We again rely on the requirement in §438.206(b)(1) and §438.206(b)(4) that MCOs, PIHPs, and PAHPs must have adequate provider networks or, if the MCO, PIHP, or PAHP is unable to provide them, must adequately and timely provide these services out of network.

6. Coordination and continuity of care (Proposed §438.208)

Proposed §438.208 contained provisions specifying how the care of Medicaid beneficiaries enrolled in MCOs and PIHPs is to be provided in order to promote coordination and continuity of care, especially with respect to individuals with special health care needs. In proposed paragraph (a) we allowed for two exceptions to some of these coordination and continuity of care provisions. In the first instance, provisions pertaining to some screening, assessment and primary care requirements would apply to PIHPs as the state determines appropriate, based on the scope of the PIHP's contracted services and the way the state has organized the delivery of managed care services. In the second instance, for Medicaid-contracting MCOs that serve certain Medicaid enrollees also enrolled in Medicare+Choice plans and receiving Medicare benefits, the State similarly determines, based on the services it requires the MCO to furnish to dually eligible enrollees, the extent to which the MCO must meet certain screening, assessment, referral, treatment planning, primary care and care coordination requirements. In proposed paragraph (b) we put forth requirements for the state Medicaid agency to identify certain enrollees with special health care needs and to further identify these enrollees to its enrollment broker, if applicable, and contracting MCOs and PIHPs. In proposed paragraph (c) we specified requirements for the screening and assessment of individuals with special

health care needs. In proposed paragraph (d) we specified requirements for referrals and treatment plans for MCO and PIHP enrollees determined to have ongoing special conditions that require a course of treatment or regular care monitoring. These requirements addressed access to specialists and the development of treatment plans. In proposed paragraph (e) we specified requirements pertaining to MCO and PIHP care coordination programs, including requirements that these programs: provide each enrollee with an ongoing source of primary care, coordinate each enrollee's health care services, appropriately share with other MCOs and PIHPs the results of any screenings or assessments in order to prevent unnecessary burden on the enrollee, and protect enrollee privacy and confidentiality.

One commenter heartily endorsed §438.208 of the proposed rule and urged CMS to preserve it in the final rule and monitor for compliance with it. However, many other commenters recommended that this section of the regulation include more specific or stronger requirements for States and managed care entities, particularly with respect to the care of individuals with special health care needs. Most commenters offered specific recommendations for changing this section of the regulation. We agree with these comments and have revised §438.208 as discussed below, in response to these comments.

Identification of “at risk” individuals

Comment: Many commenters recommended that we require States to identify individuals "at risk" of having special health care needs. Many of these commenters identified these individuals as: children and adults who receive SSI benefits; children in foster care; enrollees over the age of 65; enrollees in relevant, state-established, risk-

adjusted, higher-cost payment categories; and any other category of recipients identified by CMS. A few commenters recommended that we allow States to use additional State-identified categories of people who are "at risk" for having special health care needs. One commenter stated that children under age 2 and pregnant women should be identified as being "at risk" of having special health care needs. Another commenter stated that children enrolled in a State's Title V program for children with special health care needs should be included in a regulatory definition of persons "at risk" of having special health care needs.

Response: The proposed rule at §438.208(b) required States to identify individuals "with" (as opposed to individuals "at risk of having") special health care needs. For several reasons, we believe it is appropriate to retain this distinction in this final rule, and not additionally require States to identify individuals "at risk of having" special health care needs. First, States already well appreciate the increased risk that certain populations (for example, children and adults who receive SSI benefits; children in foster care; enrollees over the age of 65; and enrollees in relevant, state-established, risk-adjusted, higher-cost payment categories) have for needing special services or high levels of service. States can also readily identify these individuals. We do not believe that regulations are necessary to call States' attention to these individuals or that States need encouragement or assistance in identifying these individuals. To additionally require States to create a new administrative mechanism in order to categorize as "at-risk" those individuals who are already well-known to State Medicaid agencies and can be easily identified, would dilute the attention paid to individuals who actually have special health care needs. Instead, in §438.208(c) of this final regulation we require States to focus their

attention more closely on identifying individuals who actually have special health care needs. Second, the concept of "at risk" of having special health care needs (beyond the categorical groups discussed above) is widely recognized as difficult to put into operation.

Well-known researchers in this field have explicitly declined to address the concept of "at risk" when developing screening tools to identify children and adults with special health care needs. Because the science in this area is still elementary, we believe it is premature to ask States to implement this concept at this time. Finally, we note that commenters did not agree among themselves on which populations should be included in a category of "at risk of having" special health care needs. For these reasons, in this final rule we do not require States to identify individuals "at risk" of having special health care needs.

Definition of individuals with special health care needs

Comment: Many commenters recommended that proposed §438.208(b) should specify certain groups of individuals as "having" special health care needs. Many of the recommended groups were identical to the groups identified by other commenters as individuals who should be considered "at risk" of having special health care needs. Specifically, the following groups were recommend by many commenters: children and adults who are receiving SSI benefits; children in foster care; enrollees over the age of 65; enrollees in relevant, state-established, risk-adjusted, higher-cost payment categories; and any other category of recipients identified by CMS. Many commenters also identified children under age 2 and other enrollees known by the State to be pregnant or having other special health care needs as categories of persons requiring special attention and about whom the State should notify the MCO/PIHP of their having a special health care need.

Other commenters stated that proposed §438.208(b) should specify a threshold or minimum definition of persons with special health care needs. One commenter stated that the definition should be as follows, "Individuals with special health care needs include adults and children who daily face physical, mental, or environmental challenges that place at risk their health and ability to fully function in society (for example, individuals with mental retardation or serious chronic illnesses, pregnant women, children under the age of 7, children in foster care or out-of-home placement, and individuals over age 65)." Other commenters stated that children with special health care needs should be defined consistent with the Department's Maternal and Child Health Bureau's definition which reads, "Children with special health care needs are those who have or are at elevated risk for chronic physical, developmental, behavioral, or emotional conditions and who also require health and related services of a type or amount not usually required by children."

In contrast, several commenters expressed support for allowing States to define which populations need to be identified and how to identify them. One commenter asked us to confirm that the proposed rule would allow States the flexibility to define "individuals with special health care needs." Another commenter stated that the requirement for States to identify enrollees with special health care needs and identify these enrollees to its enrollment broker (if applicable) and MCOs should be eliminated. The commenter stated that this requirement is neither feasible nor practical because (1) the State does not have a mechanism to identify persons with special health care needs - other than individuals who receive SSI; (2) enrollees may not choose to reveal information about their health, which should be held between the enrollee and his or her provider, and possibly the health plans; and (3) the appropriate mechanism for identifying a person with

a special health care need is through an assessment which is required elsewhere in the regulation.

Response: In our report to the Congress, Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care, dated November 6, 2000, we identified, "the presence or increased risk of disability," as a shared characteristic of populations with special health care needs. We identified 6 populations as examples of groups that had an increased prevalence or risk of disability: (1) children with special health care needs; (2) children in foster care; (3) individuals with serious and persistent mental illness and/or substance abuse; (4) individuals who are homeless; (5) older adults with disabilities; and (6) non-elderly adults who are disabled or chronically ill with physical or mental disabilities. However, this same report, while calling these groups to the attention of States, recognized the difficulty that States face in identifying not just population *groups* that have an increased prevalence or risk of disability, but in identifying *individuals* who actually have a special health care need. Because of this, we entered into a contract with the Foundation for Accountability (FACCT) to produce a reference manual for State Medicaid agencies and other interested parties. The manual will present and discuss reliable and valid approaches to identifying individuals who have special health care needs. In addition, we asked FACCT to develop a new screening tool that can be used to help identify adults with special health care needs. This adult screener has now been developed and tested. It, along with other valid and reliable approaches to identifying adults and children with special health care needs, will be included in the reference manual for States. Because this research conducted for us by FACCT has documented that there are different ways (with varying degrees of sensitivity, specificity,

and resource implications) to identify individuals with special health care needs, we do not believe it appropriate to require one approach, and thereby one definition. Rather, we encourage States to review these different approaches, in conjunction with beneficiaries and stakeholders, as a part of their State quality strategy developed under §438.204, and select the approach or approaches to identifying individuals with special health care needs that best complements the design of the state's Medicaid program and managed care initiatives.

Comment: Many commenters recommended that States also be required to identify enrollees with special health care needs to PAHPs and PCCMs.

Response: We agree with the commenters and we have revised §438.208(c) to include PAHPs. However, we have not applied these provisions to PCCMs because, as noted elsewhere in this preamble, the statutory provisions of the BBA, which authorized these quality requirements, apply only to prepaid, capitated forms of managed care.

Screening and assessment

Comment: Many commenters expressed confusion over the use of the words "screening" and "assessment" in §438.208(c) of the proposed rule. One commenter erroneously stated that the provisions for screening and assessment of special needs individuals were not contained in the proposed regulation. Many commenters stated that the proposed rule did not differentiate between the words, "screening" and "assessment." One commenter urged us to specify that an initial screen must be sufficient to identify individuals with special health care needs and facilities that can meet those needs, and that a health assessment must be comprehensive and include a physical examination.

Response: We agree that the proposed rule provisions at §§438.208(b) and (c) respectively calling for "State responsibility to identify certain enrollees with special health care needs," and "Screening and assessment" are confusing, in part because of some redundancy. The proposed rule intended to convey that identification of individuals with special health care needs should be accomplished through some form of screening. Therefore, we have revised §438.208(c) and replaced the word "screening" with the words, "mechanisms to identify." This change is supported by information from several experts in screening who reminded us that screening tools by their very nature are not perfect, and that subsequent follow-up through a more intensive assessment is needed in order to better determine if an individual's special health care needs actually require a course of therapy or monitoring. We also made other changes to the organization of this section in order to better distinguish the identification activity from the assessment function.

However, we did not, as requested by one commenter, specify that an initial screen (identification mechanism) must be sufficient to identify facilities that can meet an individual's special needs. We believe that determining appropriate facilities, when care in a facility is needed, should not be based on the results of a screen or identification mechanism, but upon an assessment and ongoing communication between the patient and his or her health care provider(s). We further did not explicitly state in §438.208(c)(2) that the enrollee's health assessment must be comprehensive because we believe that "comprehensive" is subject to varying interpretations, and therefore is not readily able to be reliably monitored or consistently enforced by CMS. Further, the provisions in §438.208(c)(2) already require assessments to "identify any ongoing special conditions of

the enrollee that require a course of treatment or regular care monitoring" and that the assessment mechanisms must use appropriate health care professionals. We also have not required that the assessment include a physical examination, because we believe that for some individuals, a course of treatment or regular care monitoring might be determined to be unnecessary without a physical examination. We therefore defer to States to set further standards for assessment, noting that these standards for identification and assessment are included as part of a States' quality strategies under §438.204. Therefore, any State standards for assessment will be developed with the input of Medicaid beneficiaries and other stakeholders. We believe that any greater specificity in requirements pertaining to assessments should be developed as a part of this process.

Comment: One commenter stated that proposed §438.208(c) failed to quantify what will be substantial burden associated with the requirements for screening and assessment.

Response: It would be very difficult to more accurately quantify the overall impact and burden of this provision of the regulation because of the variation in State programs and how States will choose to implement these provisions. In §438.208(c) of the final rule we have retained State flexibility in identification, assessment, treatment planning for individuals with special health care needs, and with respect to how provisions will be applied to MCOs, PIHPs, and PAHPs that serve dually eligible enrollees. Because of our desire to allow States to have this flexibility, and the variations in practice that currently exist within the managed care industry, it is not possible to more accurately quantify the burden of these provisions.

Comment: One commenter stated that it could not comply with the requirement stated in the preamble to proposed §438.208 that in instances when an MCO is not able to

meet requirements for screening or assessment for an individual enrollee, because, for example, it is not possible to contact the enrollee or the enrollee refused to respond to the MCO, that the MCO ensure that the reason why the enrollee could not be screened or assessed be documented in the enrollee's medical record. The commenter stated that it does not own its contracted providers and does not have the ability to enforce the requirement.

Response: We disagree with the commenter. We believe that MCOs can include this as a requirement in their written agreements with participating providers. However, the commenter is incorrect in indicating that we have required this in the preamble. Rather, the preamble states that an MCO or PIHP “should” take steps to ensure that this information is documented.

Identification

Comment: One commenter asked us to clarify CMS's goal with respect to individuals with special health care needs given the commenter's observation that these individuals will have great variability in the coverage and care they will receive between States. One commenter stated that §438.208(b) of the proposed rules did not emphasize clearly the importance of identifying all persons with special health care needs. A few commenters expressed concern that the proposed rule did not contain provisions that would require the State to have a strategy to identify enrollees with special health care needs. One commenter stated that the regulation does not contain requirements that MCOs have procedures in place to identify individual enrollees with serious and multiple medical conditions, "whether they be physical-health, mental health, or substance-abuse related in

nature." The commenter maintained that CMS must include these provisions. A few commenters stated their support for a requirement that MCOs must screen all enrollees to detect special health care needs. A few commenters also stated that each MCO and PIHP should be required to implement a mechanism to identify enrollees who develop special health care needs after they enroll in the MCO or PIHP. One commenter asked if CMS would be monitoring States with respect to the requirement in §438.208(b) pertaining to State's responsibility to identify certain enrollees with special health care needs, and if so, if the monitoring will use a tool that has been developed for CMS by FACCT.

Response: We have revised §438.208(c)(1) and (c)(2) to clarify our goals with respect to individuals with special health care needs and emphasize the importance of identifying the individuals. We did not, as one commenter directed, require MCOs to have procedures in place to identify individual enrollees with serious and multiple medical conditions, "whether they be physical-health, mental health, or substance-abuse related in nature," because we believe that the State should be the one to consider the issues as it develops its mechanism to identify individuals with special health care needs, as part of its quality strategy, and with the input of Medicaid recipients and other stakeholders. In our revisions, we also did not require each MCO and PIHP to implement a mechanism to identify enrollees who develop special health care needs after they enroll in the MCO or PIHP. We believe that the extent to which this should occur should be considered by the States in the context of the States' overall strategy and mechanism for identifying individuals with special health care needs. Finally, we affirm that CMS will be monitoring States with respect to the requirement to identify enrollees with special health care needs. However, we note that the tool that has been developed for CMS by FACCT

is a screening tool, not a monitoring tool. Additionally, it is one of several screening tools that will be shared with States for their discretionary use. Therefore, the FACCT tool is not likely to be used by CMS for monitoring activities.

Assessment

Comment: One commenter stated that the proposed rule does not contain provisions that MCOs assess the condition of individual enrollees with serious and multiple medical conditions. The commenter maintained that CMS must include these provisions. Another commenter stated that the regulation should specify groups of beneficiaries for whom special health assessments should be required so that there will not be significant variation in access and quality of care among the various state Medicaid programs. In contrast, other commenters expressed support for the provisions of the regulation pertaining to assessment of people with special health care needs and for allowing states and plans to develop timelines and procedures that meet the needs of their enrolled population. Still other commenters further expressed support for allowing States to determine how to assess individuals with special health care needs.

Response: The final regulation contains requirements that MCOs (and also PIHPs and PAHPs at the discretion of the State) assess individual enrollees with special health care needs. We believe that individuals with "serious and multiple medical conditions" are included in the concept of special health care needs, and intend that States' mechanisms to identify individuals with special health care needs will identify individuals with serious and multiple medical conditions. However, in §438.208(c)(1) we allow States the discretion of determining how to identify individuals with special health care needs, and

therefore how to implement this concept. Consistent with this position, we do not believe that we should specify groups of beneficiaries for whom special health assessments should be required.

Initial assessments

Comment: One commenter expressed concern that the proposed regulation does not require MCOs or PHPs to conduct initial assessments of all new Medicaid enrollees, noting that Medicare+Choice plans are required to conduct the assessments.

Response: We used the term "initial assessment" in a Medicaid proposed rule published on September 29, 1998 (63 FR 52022) to implement these same statutory provisions. Since that time, we have received numerous and ongoing comments that the purpose and scope of an "initial" assessment has not been well understood. The words "initial assessment" do not appear in widespread use in the private sector or in health services research or policy studies. We have attempted to address this problem in subsequent versions of the regulation, and in §438.208(c)(1) and (c)(2) of this final regulation, by dropping the terminology "initial assessment" and separating out what we believe are the two essential activities; that is, identifying individuals who have special health care needs, and assessing their needs. We do not believe it necessary to further specify the need for primary care providers operating under the auspices of an MCO, PIHP, or PAHP to assess the health of their patients, because we believe this to be a well-established component of primary health care.

Timeframes

Comment: One commenter stated that the regulation must ensure that people with

identifiable risks for having special health care needs receive an expedited review of their health care needs. Many commenters stated that the final rules should include a health assessment soon after enrollment to identify pregnant women's health care needs and course of treatment. Many other commenters stated that the regulation should specify timeframes for managed care entities to screen and assess individuals with special health care needs, individuals "at risk" of special health care needs, and other enrollees. Many of these commenters recommended a variety of specific timeframes as follows. MCOs and PHPs should be required to: (1) screen enrollees identified as "*at risk*" by the State within 30 days of the enrollees being so identified; (2) screen all other enrollees within 90 days of enrollment to determine whether the enrollee is pregnant or has a special health care need; (3) for any screened enrollee identified as being pregnant or having special health care needs, provide a comprehensive health assessment as expeditiously as the enrollee's health condition requires, but no later than 30 days from the date of the identification; (4) for enrollees identified by the State as being pregnant, or who have self-identified as being pregnant or having special health care needs, provide a comprehensive health assessment within 30 days without needing an initial screen. Other commenters stated that screening should be performed on enrollees identified by the State as having special health care needs within 30 days after having been so identified by the State. One commenter stated that the regulation should require initial assessment of each pregnant woman by her MCO as soon as possible, but always within 30 days of enrollment. The commenter also stated that standards for individuals with complex and serious medical conditions should be similarly revised. Another commenter recommended that each MCO and PHP be required to make a best effort to screen the following individuals within 30 days of their being

identified: children and adults who receive SSI, children in Title IV-E foster care, enrollees over the age of 65, and enrollees in relevant, state-established, risk-adjusted, higher cost payment categories, and other categories identified by CMS. This commenter also recommended that each MCO and PHP be required to make a best effort to assess individuals who are pregnant or who have a special health care need within 30 days of their being identified. Another commenter recommend that disabled children and adults, foster children, enrollees over the age of 65, pregnant enrollees and infants and toddlers be screened by their MCOs within 30 days; other MCO enrollees should be screened within 90 days. Several other commenters, however, did not recommend a specific timeline. One commenter stated that timelines should be specified in advance by the State and approved in advance by CMS.

In contrast, one commenter stated that proposed §438.208(c) and (d) that pertain to assessment and treatment of people with special health care needs are realistic and allow States and plans to develop timelines and procedures that meet the needs of their enrolled population. Another commenter expressed support for allowing States the authority to determine workable timeframes for their individual programs.

Response: We have carefully reviewed all the suggestions, and we do not believe it best for the Federal government, rather than the States, to establish timeframes specifying when all managed care entities are to screen and assess individuals with special health care needs, individuals "at risk" of special health care needs, and other enrollees. We believe that it would be more appropriate and effective for screening and assessment timelines to be established by the State agency, in consultation with beneficiaries and other stakeholders, taking into consideration access and availability standards set by the State,

the definitions and mechanisms chosen by the State agency to identify individuals with special health care needs, the character of the state's managed care marketplace, and State and/or local standards in both the public and private marketplace. With respect to the comment that timelines should be specified in advance by the State and approved in advance by CMS, we note that because we believe that any necessary timelines should be established by the State based on State considerations, CMS would not likely have more relevant information than the State, on existing access and availability standards set by the State, definitions and mechanisms chosen by the State agency to identify individuals with special health care needs, the character of the State's managed care marketplace, and State and/or local standards in both the public and private marketplace. We therefore decline to require prior Federal approval of State timelines.

Treatment plan

Comment: Many commenters supported our proposed §438.208(d) that pertains to a treatment plan for enrollees with special health care needs, but disagreed with the provision in §438.208(d)(2) that states that the decision is left to the discretion of the enrollee's MCO/PHP of whether or not an individual with special health care needs would receive a treatment plan. Many commenters further stated that the regulation should indicate the individuals for whom health plans must develop and implement treatment plans, including individuals with special health care needs and pregnant women, particularly those pregnant women at high risk such as those with gestational diabetes or with a history of miscarriages.

Many commenters also suggested a number of additional provisions be added to the

requirements for a treatment plan; specifically, that treatment plans: (1) be appropriate to the enrollee's identified and assessed conditions and needs; (2) be for a specific period of time and updated periodically; (3) specify a standing referral or an adequate number of direct access visits to specialists; (4) ensure adequate coordination of care among providers; (5) be developed with enrollee participation and (6) ensure periodic reassessment of each enrollee as his or her health condition requires. A few commenters stated that the treatment plan should be required to be appropriate to the standard of care for the enrollee's condition and identified needs. Other commenters noted that the Medicare+Choice regulations require a treatment plan for all enrollees with serious medical conditions. One commenter stated that the regulation should add a new provision requiring that, "the MCO or PHP must continue the existing treatment plan of an enrollee until an initial assessment of that enrollee occurs." The commenter stated that this provision would address the adverse effects that individuals can experience when there is an interruption in the ongoing clinical treatment of their illness or health condition. One commenter recommended the inclusion of requirements that treatment plans include direct access to specialists as required by the treatment plan and that the treatment plan be updated periodically by the physician responsible for the overall coordination of the enrollee's health.

In contrast, a few other commenters supported the provisions of the regulation pertaining to assessment and treatment of people with special health care needs, stating that the provisions are realistic and reasonable and allow states and plans to develop timelines and procedures that meet the needs of their enrolled population. One commenter stated that the enrollee, provider, and MCO clinical staff should determine the provisions that need to

be included in a member's treatment plan. One commenter expressed support for allowing states to determine the extent to which MCOs must put in place mechanisms to allow enrollees to participate in the development of the treatment plan. One commenter recommended that an additional exemption be created in paragraph (a) with respect to the requirement that there be consultation with the primary care provider in the development of the treatment plans. The commenter noted that in his or her State, fee-for-service primary care providers are not a part of the specialty managed care network, and are not responsible for coordinating their primary care with mental health professionals. The commenter recommended that a new exception be added as section 438.208-(a)(2) (iii) "to consult with the enrollee's primary care provider in the development of a treatment plan as specified in paragraph (d)(2) of this section."

Response: We have revised §438.208(c)(2) of this regulation, that left the decision of whether or not an individual with special health care needs receives a treatment plan up to the discretion of the enrollee's MCO, PIHP, or PAHP. We agree with many of the commenters that this decision should not be left up to the MCO, PIHP, or PAHP and have revised the regulation to give States the authority to determine the extent to which treatment plans would be required. States will be required to address this as a component of their quality strategy and to develop these standards with input from Medicaid recipients and other stakeholders.

For a variety of reasons, we disagree with commenters that we should add certain other requirements for treatment plans; that is that treatment plans be required to: (1) be appropriate to the enrollee's identified and assessed conditions and needs; (2) be for a specific period of time and updated periodically; (3) ensure periodic reassessment of each

enrollee as his or her health condition requires; and (4) be required to be appropriate to the standard of care for the enrollee's condition and identified needs. We found a number of these requirements to be vague and therefore difficult to monitor and enforce, and not providing significant benefit to beneficiaries; for example., "be for a specific period of time and updated periodically," "appropriate to . . . conditions and needs" and "appropriate to the standard of care for the enrollee's condition and identified needs." In addition, we note that two of these proposed additions to treatment plan requirements are more strongly addressed elsewhere in this section. The recommended requirement that the treatment plan specify a standing referral or an adequate number of direct access visits to specialists is addressed in paragraph (c)(4), *Direct Access to Specialists*, which states that, "For enrollees determined through assessment to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs." The recommended requirement that the treatment plan ensure adequate coordination of care among providers is addressed in paragraph (b), *Primary care and coordination of health care services for all MCO, PIHP, and PAHP enrollees*. We also did not add a requirement that, "The MCO or PHP must continue the existing treatment plan of an enrollee until an initial assessment of that enrollee occurs." We believe that the situation, which the commenter has identified, is addressed by the provisions at §438.208(b) pertaining to primary care and coordination of health care services.

Direct access to specialists

Comment: One commenter stated that proposed §438.208(d) that pertains to direct access to specialists should be clarified that direct access to a specialist should be a determination made in concert with the primary care physician, health plan, patient, and specialist based on each patient's specific circumstances, not made through a screening instrument that identifies an individual as having special health care needs. Another commenter expressed support for the regulatory provisions allowing States to determine MCOs mechanisms through which Medicaid enrollees with special health care needs will have direct access to specialists.

Response: We agree that a decision about access to specialists should not be based on the results of screening. In §438.208(c)(4) of the final rule, we clarify that access to specialists should be made as a result of a more detailed assessment using (consistent with §438.208(c)(2)) "appropriate health care professionals." We believe appropriate health care professionals include the enrollee's primary care provider, but not necessarily the MCO or a specialist. Participation of the enrollee in this decision is guaranteed under the provisions in §438.100 (b)(2)(iv) pertaining to the enrollee's right to participate in decisions regarding his or her health care.

Exemptions

Comment: One commenter expressed support for the exemption allowing State Medicaid agencies to determine to what extent any MCO that serves enrollees who are also enrolled in a M+C plan and receive Medicare benefits must meet the screening and assessment, referral and treatment plan, and primary care and coordination requirements of

proposed §438.208(c), (d), and (e)(1) (now §438.208(b) and (c)). The commenter recommended that dual eligible enrollees receive one screening and assessment that satisfies requirements for Medicare+Choice.

Response: We appreciate and agree with the commenter's support for the provision in §438.208(b) and (c) that allow State Medicaid agencies to determine to what extent any MCO that serves enrollees who are also enrolled in a M+C plan and receive Medicare benefits must meet requirements pertaining to coordination, identification, assessment, and treatment planning. We agree that it is desirable for dual eligible enrollees to receive one screening and assessment that satisfies requirements for both Medicaid and Medicare+Choice, but we are not imposing this requirement at this time, in recognition of the operational and policy issues that first must be addressed in order to accomplish this and because it may not be feasible in all instances.

Patient confidentiality and sharing of information

Comment: One commenter expressed concern about the provision of proposed §438.208(e)(3) which would require MCOs and PIHPs to share with other MCOs and PIHPs serving an enrollee, the results of its screening and assessments so that those activities need not be duplicated. The commenter understood of the intent of the provision but expressed concern over possible effects on patient confidentiality. The commenter offered no specific recommendation to address these competing concerns. Another commenter noted that the requirements might present concerns about patient confidentiality if MCOs are not able to obtain enrollee consent for the sharing of information. One commenter supported the proposed regulation's provision in §438.208(e)(4) pertaining to

the protection of enrollee privacy.

Response: We also share commenters' concerns about protecting the privacy of patient information. For this reason, we have retained the provision, now at §438.208(b)(4), that states that, ". . . in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that they are applicable.

Primary care and coordination program

Comment: One commenter noted that the proposed regulations in §438.208(e) allowed primary care coordination to be conducted by "a person or entity." The commenter stated that it is inappropriate to allow MCOs or PHPs to delegate management of an enrollee's health care to an unlicensed or non-credentialed person or entity. The commenter recommended that primary care coordination be performed by a health care professional, as that term is defined in proposed §438.102. One commenter recommended that CMS should describe in the regulation necessary coordination efforts and include specific references and examples.

Response: We have retained the wording, "a person or entity" in this final rule to acknowledge that sometimes care coordination might be performed by an organization, such as a Federally Qualified Health Center (FQHC), as opposed to an individual. We have not described in the regulation necessary coordination efforts and specific references and examples because we believe that there are more appropriate vehicles than this regulation for disseminating best practices, reference materials and examples of care coordination.

Monitoring

Comment: One commenter recommended that CMS: (1) closely monitor State agency and managed care entity procedures to identify any problems or disruptions in the continued treatment of patients with mental illness, including a substance abuse disorder; (2) provide direction to the State or State agency to facilitate effective solutions; and (3) use CMS resources to assure that continuity and coordination is maintained.

Response: We will closely monitor State agencies and their managed care initiatives to identify any problems or disruptions in the services or treatment of all Medicaid enrollees, including enrollees with special health care needs such as mental illness and/or substance abuse. When deficiencies are found, we typically direct the State agency to undertake solutions and use our resources to assure that the solutions are effective.

Factors that hinder access

Comment: Many commenters recommended an addition to MCO/PIHP coordination provisions at proposed §438.208(e) to require plans to have in effect procedures to address factors, such as lack of transportation, that may hinder enrollee access to health care treatments or regimens.

Response: We do not agree with this recommendation. We know that many States and MCOs, PIHPs, and PAHPs in the absence of federal regulations, have in effect procedures to address factors, such as lack of transportation, that may hinder enrollee access to health care treatments or regimens. However, we believe that the extent to which these procedures should be the responsibility of the MCO, PIHP, or PAHP in contrast to

the State agency or other agent of the State, is a decision best made by the State agency.

Maintenance of health records

Comment: Many commenters recommended that a provision be added to require each MCO and PHP to ensure that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with certain confidentiality and accuracy requirements. Many commenters also recommended that each MCO and PHP be required to ensure that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

Response: We believe that both of these issues are already addressed in other sections of the regulation. Section 438.242, *Health Information Systems*, requires the MCO and PIHP to maintain a health information system that "collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart" and "ensures that data received from providers is accurate and complete." We believe that this requirement is a stronger and more effective standard than a requirement that each provider maintain health records that meet professional standards. In addition, §438.224, *Confidentiality*, requires each MCO and PIHP to establish and implement procedures in accordance with confidentiality requirements in 45 CFR parts 160 and 164. We believe these provisions more strongly address confidential sharing of information among providers.

7. Coverage and authorization of services (Proposed §438.210)

Proposed §438.210 set forth requirements to ensure that each contract with an MCO or PIHP identifies all services offered under the contract, and that the MCO or PIHP

establishes and follows written policies and procedures for processing requests for services in a manner that ensures appropriate beneficiary access to these services. Further, the proposed requirements would ensure that utilization management activities are not structured in a manner that is detrimental to enrollees. These standards implement sections 1932(b)(1) and (b)(4) of the Act.

In §438.210(a) we proposed that the State, in its contracts with MCOs and PIHPs, identify, define, and specify the amount, duration, and scope of all Medicaid benefits that the MCO or PIHP must furnish. Furthermore, the contract must specify what constitutes medically necessary services to the extent they are described in the State plan, and provide that the MCO or PIHP furnish the services in accordance with that provision. We believe that it is important for enrollees and providers to know that the contract includes specific information on all services available under the contract and how the State applies its medical necessity criteria. We also required that the contract be clear on coverage of services related to (1) the prevention, diagnosis, and treatment of health impairments; (2) the ability to achieve age appropriate growth; and (3) the ability to attain, maintain, or regain functional capacity.

In paragraph §438.210(b) we required that MCOs and PIHPs, and their subcontractors, have in place and follow written policies and procedures for initial and continuing authorization of services. We also required that MCOs and PIHPs consistently apply review criteria when authorizing services; consult with the requesting provider, when appropriate; and that decisions to deny requests for authorizations, or authorize a service in an amount, duration, or scope that is less than was requested, must be made by a health care professional who has the appropriate clinical expertise in treating the

enrollee's condition or disease.

In paragraph (c), we proposed that MCO and PIHP contracts provide that written notice of decisions to deny a service authorization request or to authorize the request in an amount, duration, or scope that is less than what was requested be provided to the enrollee and the provider. The notice to the enrollee must be in writing.

In paragraph (d), we proposed timeframes for decisions to authorize services. For standard authorization decisions, the notice must be provided as expeditiously as the enrollee's health condition requires and within State-established timeframes that do not exceed 14 calendar days following the request for service. A 14 calendar-day extension would apply at the enrollee's or provider's request or if the MCO or PIHP justifies a need for additional information and how the extension is in the enrollee's interest. We believe that an extension would be in the enrollee's interest when more information is needed for the MCO or PIHP to authorize the service and failure to extend the timeframe would result in a denial of the authorization.

For expedited authorization decisions, we proposed that the MCO or PIHP have a maximum of 3 working days after receipt of the request to make a decision. This period could be extended for 14 days under the same circumstances as apply for standard decisions.

In proposed §438.210(e), we required that each MCO and PIHP contract must provide, consistent with §438.6(g) and §438.210(a)(2), that compensation to individuals and entities that conduct utilization management activities not be structured so as to provide incentives to deny, limit, or discontinue medically necessary services to enrollees.

Comment: One commenter expressed the opinion that §438.210 should apply to

dental plans.

Response: We agree with the commenter. We decided to extend the provisions of §438.210 to include PAHPs as well as MCOs and PIHPs because we believe that enrollees of PAHPs need the protections provided under this section. This includes dental plans as well as other PAHPs. We note that the services included in the plans are limited to those provided for under the contract and that the provisions are not always applicable to certain PAHPs, for example, transportation PAHPs.

Comment: Several commenters recommended a Federal definition of medical necessity be included in the regulation that includes access to habilitative services. One commenter said that habilitative services are important for children and adults with severe mental impairments.

Response: We do not agree that the regulation should include a Federal definition of medical necessity. There currently exists no widely accepted national definition and at present States are allowed, under §440.230(d), to “place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures,” and have great flexibility in defining those criteria. Therefore, we do not believe it is appropriate to promulgate a national definition. However, we believe it is necessary to provide some specific guidance regarding what State contracts must include. In particular, we believe that whatever a State’s fee-for-service Medicaid program uses as medical necessity criteria should not be further restricted by Medicaid MCOs, PIHPs, and PAHPs. Making this clear to all parties should decrease the potential for dispute. If the State’s fee-for-service medical necessity criteria address whether a service is needed “to attain, maintain or regain functional capacity,” the regulation requires the contract with the MCO, PIHP, or

PAHP to address this as well. We believe this would address the extent to which habilitative services are considered medically necessary. While we are not mandating that specific services must be covered to meet these goals, the contract must clearly address the extent of each MCO's, PIHP's, and PAHP's responsibility to provide such services.

Comment: One commenter asked that the words "enrollee's ability to attain, maintain, or regain maximum function...could be jeopardized" should be deleted from the definition of medical necessity, as this definition is so broad that it could be applied to nearly all medical necessity determinations.

Response: These words are not part of a definition of medical necessity. Rather, they make clear that State policies related to medical necessity under fee-for-service address any of the items listed in §438.210(a)(4)(ii), then the State's contract with an MCO, PIHP or PAHP must also address these items. We believe this greater clarity will decrease the potential for disputes, among beneficiaries, the State and MCOs, PIHPs, and PAHPs.

Comment: One commenter expressed concern that the proposed rule allows MCOs and PIHPs to limit services on the basis of the medical necessity definition and utilization controls. This commenter noted that the EPSDT provision of the Medicaid statute ensures children the full range of needed health care services and recommended specific language in the regulation to ensure this end.

Response: Under §440.230(d) States already have the authority to "place limits on a service based on such criteria as medical necessity or on utilization control procedures" and have great flexibility in defining those criteria. This provision also applies to services provided through the EPSDT program.

This managed care regulation does not affect any of the pre-existing EPSDT regulations. Furthermore, some States may choose to provide EPSDT services outside of the managed care contract. We believe it is redundant and unnecessary to repeat all existing requirements in this regulation, which focuses on managed care programs.

Comment: One commenter expressed concern that an MCO should not be “placed in the middle of a decision” by a provider to deny a service based on “field experience and clinical documentation”. The commenter said that their State has consumer safeguards in place, both in the coverage and authorization process and grievance and appeal process, to protect enrollees.

Response: Section 1932(b)(4) of the Act requires that MCOs have internal grievance procedures for enrollees. Therefore, we must provide for such a process in the regulation and the MCO or PIHP must approve or disapprove a provider’s decision.

Comment: Several commenters asked that the notice of action and right to appeal be removed in the case of a physician who denies a request for service, as this is not a realistic requirement and would trigger service continuation requirements. The commenter stated that there is no practical way for an MCO to know that a physician counseled against a medical service. Also, the requirement is unduly burdensome, particularly as it relates to modified requests for service authorizations that are agreed to by the requesting provider. One commenter said that this requirement is inconsistent with industry and Medicaid practice.

Response: We acknowledge that it is difficult for an MCO or PIHP to know when a physician counseled against a service and that it would be burdensome to require physicians to provide notice of denial to enrollees or to inform the MCO or PIHP that a

requested service was not provided. To address this issue, in the final rule, at §438.404(b)(1), we have revised the regulation to specify that the enrollee has the right to appeal a denial by the MCO or PIHP. The physician's decision to provide a service does not trigger an appeal right. This will require the enrollee who wishes to receive a service that the physician will not provide to contact the MCO or PIHP to request approval of the service. A denial of the service at that point by the MCO or PIHP will constitute an action that may be appealed by the enrollee. In response to the comment related to service continuation, we note that services must be continued only if they have been approved in advance by the MCO or PIHP, or by a provider acting on behalf of the MCO or PIHP.

Comment: One commenter asked for clarification that §438.210 applies to provider requests for authorization and not when a beneficiary requests a service that the provider does not find to be medically necessary.

Response: As explained in the previous response, we specify in the final rule that the appeal right is triggered when an action is taken by the MCO or PIHP to deny a requested service or authorize it in an amount, duration, or scope that is less than was requested by the enrollee.

Comment: One commenter asked if the regulation intends to require that a "clinical peer" within the MCO be used to deny a service authorization. If so, the commenter stated that this would impose an additional requirement beyond what is required in State law (which permits any licensed physician to deny an authorization). This would require a significant change in operation for MCOs in that State.

Response: We do not use the term "clinical peer" to describe the qualifications of the health care professional who must make a service authorization decision. Rather we

say that the health care professional must have “appropriate clinical expertise in treating the enrollee’s condition or disease”. We believe that this criterion provides States latitude to specify what clinical experience will be required for individuals making authorization decisions. We also do not specify that the health care professional must be employed by the MCO or PIHP. This permits MCOs and PIHPs to contract for the services of health care professionals if they choose and the State approves.

Comment: One commenter believes that the standard set by the regulation, that prior authorization decisions be made by a health care professional who has appropriate clinical expertise, is unclear and may lead to unnecessary litigation. The commenter also noted that this standard is not imposed in FFS, nor is this expertise required at a State fair hearing.

Response: We believe that it is important that individuals who make authorization decisions for MCOs and PIHPs have appropriate medical knowledge and clinical experience when making these decisions. This supports the credibility of decisions and may be a factor in the enrollee’s decision to appeal. In FFS and State fair hearings the situation is different, but in both cases, professional clinical judgments are available. In FFS, the beneficiary has an option to seek out another provider should a physician not agree to provide requested services. For State fair hearings, beneficiaries may present medical evidence in support of their claims.

Comment: One commenter suggested changing “treating” to “assessing” or “evaluating” in regard to the health care professional who must deny or limit a service authorization request. This would allow clinicians some latitude to determine if their level of expertise is appropriate for the review. The State in which the commenter resides holds

licensed physician professionals accountable for consulting with appropriate specialists for each decision to deny care.

Response: We continue to believe that the requirement should be that health care professionals have clinical experience in treating the condition or disease under review. As noted above, we believe that the requirement provides some latitude for States to determine what experience is appropriate. We do not think it appropriate for a health care professional without clinical treatment experience to make judgments regarding treatment.

Comment: One commenter said that the lack of a definition of “appropriate” in §438.210(b)(3) is problematic. This relates to health care professionals with the expertise to deny a service authorization request.

Response: We believe that the word “appropriate” conveys a responsibility to the State to specify further criteria to meet the intent of this provision. We do not believe that Federal regulations should provide greater detail as we are not able to address all medical situations or local conditions. We believe this responsibility should rest with the States.

Comment: One commenter suggested that the health care professional denying a request for services should be required to see the patient.

Response: We do not agree that that a health care professional denying a request should be required to see the patient. We include a requirement under §438.210(b)(2)(ii) that the MCO or PIHP policies and procedures include consultation with the requesting provider, when appropriate. We believe that this requirement will ensure that the MCO or PIHP has the information needed to make an informed decision.

Comment: One commenter suggested that we add “or who has considered advice from a health care professional with clinical expertise in treating the enrollee’s condition

or disease” at the end of §438.210(b)(3).

Response: We do not agree that it is sufficient for the decision maker to rely on information gained through consultation with a clinical expert. We believe that the decision maker must be capable of rendering a decision based on his or her own expertise. Therefore, we have not revised the regulation as requested by the commenter.

Comment: Several commenters asked how we define “standard decisions,” as no definition is provided in the regulation.

Response: A standard decision is one that does not meet the criteria for an expedited decision. These criteria are specified in §438.210(d)(2) and again at §438.410(a).

Comment: Many commenters urged that expedited authorizations be required to be made within 72 hours rather than in 3 working days. A 72-hour standard would ensure that decisions are made in a timeframe consistent with the urgent medical needs of the case. This would also apply to Medicaid enrollees the same protections that apply to other private and public health programs and are consistent with the provision of the patient’s bill of rights.

Response: In §438.210(d)(2), we have retained the maximum timeframe for expedited decisions at 3 working days because this provides a State flexibility to set a timeframe that it believes appropriate while protecting beneficiaries by stipulating a maximum timeframe. The regulation also requires that the decision be made “as expeditiously as the enrollee’s health care condition requires.” This provides beneficiaries further protection when a quicker decision is necessary because the timeframes set by the State would seriously jeopardize the enrollee’s life or health.

Comment: Many commenters disagreed with the provision that would allow MCOs and PIHPs to extend the timeframe for expedited authorization decisions by 14 days when the extension is in the interest of the enrollee. The commenters believe that this provision undermines the strength of the shorter timeframe for expedited decisions and lessens the likelihood that the expedited timeframe will be met in practice. They also note that the provision is inconsistent with the Employee Retirement Income Security Act (ERISA) rules governing employer-sponsored groups and the patients' rights legislation supported by the Administration .

Response: We retain the provision that allows the MCO or PIHP to extend the decision period by up to 14 days when the extension is in the best interest of the enrollee. We believe this protects the enrollee in situations in which sufficient information is not available to authorize a service at the end of the 3-day period. Without this provision, the enrollee would be denied the service and would need to appeal the denial to pursue the request. With this provision, the MCO or PIHP can continue to pursue the outstanding information and, ultimately, approve the request, if appropriate.

Comment: One commenter suggested that the timeframe for authorization should begin when all information necessary to make a decision is received by the MCO and not when the enrollee's request is first denied.

Response: We have not accepted this comment because this would require a separate decision that all information needed to make a decision has been received. The authorization decision is generally made when information sufficient to make a decision is reviewed by the deciding health care professional. We believe that it is an important protection for the enrollee that the timeframe begin when the request for service is denied.

It also provides an incentive for the MCO or PIHP to promptly gather information needed for a decision.

Comment: One commenter said that the 14-day extension should not apply when MCOs and PIHPs make late requests for additional information.

Response: It would be difficult to assess when a request for information is late, as the deciding health care professional may find a need for additional information when reviewing the information associated with the request. Therefore, we do not believe that this is an appropriate standard to use.

Comment: One commenter asked that the regulation not provide a national timeframe for authorization decisions. Rather, States should be required to set standards based on community norms.

Response: We note that the timeframe provided in the regulation is a maximum timeframe; States may set shorter timeframes if they choose. We continue to believe that it is appropriate to set a maximum national timeframe as an important protection to Medicaid managed care enrollees.

Comment: Several commenters asked for a provision to prohibit requests for authorizations from having unnecessary or unduly burdensome information requirements for enrollees or providers. The commenters believe that such a provision is necessary to prohibit MCOs and PIHPs from increasing the “hassle factor” on physicians as a means of cutting costs.

Response: It is not possible or reasonable to regulate against unnecessary or burdensome information requirements. States have other tools to ensure that MCOs and PIHPs with which they contract are not deliberately making it difficult for enrollees to

access services. These include monitoring grievances and appeals by enrollees; requirements for adequate provider networks, as providers are unlikely to contract with MCOs or PIHPs that make it difficult for them to provide services; and other monitoring by the State.

Comment: Many commenters asked that the regulation include a provision to require that MCO and PIHP policies and procedures for decisions on coverage and authorization of services reflect current standards of medical practice. One commenter believes that omission of such a provision suggests that providers would be permitted to have policies and procedures that do not reflect current medical practice standards.

Response: We believe that such a provision is unnecessary as the requirement related to medical necessity will ensure that coverage and authorization decisions reflect current standards of medical practice. The omission of this as a requirement in no way implies that States or CMS sanction or permit practitioners to have policies and procedures contrary to current standards of medical practice. On the contrary, the provision on practice guidelines at §438.236 requires that MCOs, PIHPs, and PAHPs (where appropriate) adopt and disseminate practice guidelines to their contracting providers to ensure that enrollees' care is consistent with the latest and most effective clinical practices.

8. Provider selection (Proposed §438.214)

Proposed §438.214 required State Medicaid agencies to ensure that contracted MCOs and PIHPs have written policies and procedures for the selection and retention of providers and a documented process for the initial credentialing and recredentialing of

providers. It also required that MCOs and PIHPs not discriminate against providers who serve high-risk populations or specialize in conditions that require costly treatment. Finally, it prohibited MCOs and PIHPs from contracting with providers excluded from participation in Medicare and State health care programs.

Comment: One commenter asked that language be added under §438.214(b) to say “state-licensed providers” and add “of primary care, including at a minimum, physicians, psychologists, physician assistants, midwives, and nurse practitioners”.

Response: The definition of provider, at §400.203, as amended by this regulation, requires that the individual or entity be legally authorized by the State to deliver health care services. Therefore, it is not necessary to say “state-licensed providers.” In addition, it is not necessary to specifically list types of providers, as the definition of provider is broad enough to encompass these types of individuals or entities.

Comment: Many commenters recommended that we apply the Medicare+Choice credentialing rules to Medicaid MCOs, PIHPs, and PAHPs.

Response: We have decided not to apply the Medicare+Choice credentialing rules. Since each State Medicaid managed care program is unique, we do not believe that it would be appropriate to create detailed national standards. The regulation was written to promote State flexibility to manage their programs. However, we agree that there should be a uniform State standard for credentialing and recredentialing and have revised §438.214(b) to require the State to set this standard policy. These policies and procedures must, at a minimum, include a documented process for credentialing and recredentialing, not discriminate against providers that serve high-risk populations or specialize in conditions that require costly treatment, and may not employ or contract with providers

excluded from participation in Federal health care programs. We also revised §438.214 to apply it to PAHPs, based on general comments requesting that all the provision of subpart D apply to PAHPs.

Comment: One commenter expressed approval of not including specific requirements in the regulation but asked that CMS require States to use a process consistent with the credentialing guidelines of the National Committee on Quality Assurance (NCQA).

Response: We have decided not to require States to use a process consistent with NCQA's credentialing guidelines. It is up to each State to decide if they want to use these guidelines. Our regulation only requires MCOs, PIHPs, and PAHPs to implement written policies for the selection and retention of providers. However, we do require that each State set a uniform credentialing policy for all of its MCOs, PIHPs, and PAHPs.

Comment: One commenter seeks clarification that MCOs not be required to credential non-physician providers of licensed health facilities under contract to the plan if the facility itself credentials its providers.

Response: We do not address this level of specificity in the final rule. This provision speaks to the credentialing of providers and does not make a distinction between non-physician and physician providers or who does the credentialing. At a minimum, each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing providers who have signed contracts or participation agreements with the MCO, PIHP, or PAHP. Further, a provider in Medicaid managed care is defined as any individual or entity who is engaged in the delivery of health care services and is legally authorized to do so by the State in which he or she delivers the services.

Comment: One commenter stated that in the absence of a credentialing regulation, in many States, providers would set their own standards.

Response: This final rule does not allow individual providers to establish their own credentialing standards. Section 438.214(b) requires States to set uniform credentialing policies and each MCO, PIHP, and PAHP must follow this policy for credentialing providers.

Comment: One commenter expressed the opinion that a lack of specific credentialing requirements is an open door for States to lower standards for doctors who see Medicaid beneficiaries.

Response: We do not believe that States will establish lower standards for doctors who serve Medicaid beneficiaries. We allow States the flexibility to determine the credentialing policy that best fits their State's needs. The providers being credentialed must be legally authorized to deliver services in the State. Further, States must ensure that each MCO, PIHP, and PAHP maintains a network of providers that is appropriate to meet the needs of its enrolled population.

9. Enrollee Information (Proposed §438.218)

This section provided that the information requirements under §438.10 are part of a State's quality strategy. We received no comments on this section and have retained it as in the proposed rule.

10. Confidentiality (Proposed §438.224)

This section of the proposed rule required that States must ensure that MCOs and PIHPs meet the privacy requirements of subpart F of part 431 of this chapter and 45 CFR

160 and 164.

Comment: Many commenters suggested that we strengthen the regulation to make clear that monitoring and oversight do not end with inclusion of contract language. The commenters suggested the addition of the following language “The State must ensure, through its contracts *and by monitoring compliance with those contracts*, that etc.”

Response: We agree that monitoring and oversight require more than the inclusion of contract language. However, we provide for monitoring and oversight within the regulation. Under §438.204(b)(3), the State quality strategy must include procedures to regularly monitor and evaluate MCO and PIHP compliance with the contract standards.

Comment: One commenter asked if State confidentiality laws that are stricter than Federal privacy laws will continue to apply.

Response: The Federal privacy laws do not pre-empt State confidentiality laws, to the extent that State laws are stricter.

Comment: One commenter noted that the privacy regulation cross referenced in this rule does not take effect until April 14, 2003. Assuming this regulation takes effect prior to that date, the commenter asked whether the privacy rules take effect earlier for Medicaid managed care MCOs and PIHPs.

Response: The privacy rule became effective on April 14, 2001. Most health plans and providers that are covered by the new rule must comply with the new requirements by April 14, 2003. Enforcement of the privacy rule will not occur until April, 2003. This final rule does not alter these dates, nor does it impose privacy requirements in addition to those of the privacy final rule that became effective on April 14, 2001 (65 FR 82462).

Comment: Several commenters requested that the regulation make clear that the confidentiality provisions extend to minors who seek health services through Medicaid.

Response: Section 438.224, as a whole, was intended to ensure that MCOs and PIHPs have procedures to protect the confidentiality of all enrollees. We intend the term “enrollee” to encompass all enrollees, regardless of age. Further, the privacy rule provides all individuals with certain rights with respect to their personal health information, including the right to obtain access to, and request amendment of, health information about themselves. The privacy rule also has specific requirements regarding a minor and the minor’s personal representative and their control over the minor’s health care information (See 45 CFR §164.502(g)).

11. Enrollment and disenrollment (Proposed §438.226)

This section of the proposed rule provided that each MCO and PIHP contact must comply with the enrollment and disenrollment requirements and limitations set forth in §438.56. We received no comments on this section and have retained it as proposed.

12. Grievance systems (Proposed §438.228)

Proposed §438.228(a) required that the State ensure through its contracts with MCOs and PIHPs that they have grievance systems that met the requirements of subpart F. Paragraph (b) required States that delegate to the MCO or PIHP responsibility for notifying enrollees of an adverse action to conduct random reviews of the MCO, PIHP, and their providers to ensure that notices are provided in a timely manner.

Comment: Many commenters urged that the provisions of subpart F on grievances and appeals be applied to PAHPs. They believe that enrollees of these plans should have

equal rights to grieve and appeal and that States should have access to data on grievances and appeals to monitor PAHPs for quality. Another commenter said that enrollees of PAHPs should have access to grievances and appeals because managed care, by its nature, includes conflicts of interest between the plans and their enrollees.

Response: We do not agree that the grievance system required under Federal regulation should apply to PAHPs. The services provided by PAHPs are generally of a much more limited scope than those provided by MCOs and PIHPs. We note that States may extend the grievance system requirements to PAHPs, or may require another grievance and appeals process.

Comment: Many commenters suggested that the State should be required to review quality of care grievances at the request of the enrollee. Without a provision for quality of care grievances no external record exists of MCOs and PIHPs that consistently fail to adhere to basic quality standards. Another commenter stated his opposition to inclusion of a category of grievance for quality of care.

Response: The final regulation does not include a category of grievance for those related to quality of care. Rather, grievances related to quality of care fall into the general grievance category. We agree that data on grievances and appeals provide States with important information about the quality of care delivered by MCOs and PIHPs. For this reason, in §438.416, we require that States must require MCOs and PIHPs to maintain records of grievances and appeals and review that information as part of the State quality strategy. While we do not require that States review quality of care grievances, we believe that States are responsive to issues raised by enrollees related to quality and will generally review these grievances when requested.

13. Subcontractual relationships and delegation (Proposed §438.230)

Proposed §438.230(a) set forth requirements specifying that an MCO or PIHP that contracts with the State retains full accountability for any activities under its contract that it delegates to a subcontractor. Paragraph (b) required that before an MCO or PIHP delegates responsibility to a subcontractor it must (1) evaluate the prospective contractor's ability to perform the functions to be delegated, and (2) have a written agreement that specifies the activities and report responsibilities of the subcontractor and provides for revoking the delegation or imposing sanctions if the subcontractor's performance is inadequate. Paragraph (c) required that the MCO or PIHP monitor the performance of the subcontractor and conduct periodic formal reviews on a schedule established by the State.

We received no comments on this section and we have retained §438.230 as proposed.

14. Practice guidelines (Proposed §438.236)

Proposed §438.236 required that States ensure that each MCO and PIHP adopt practice guidelines that (1) are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field, (2) consider the needs of the MCO's or PIHP's enrollees, (3) are adopted in consultation with contracting health care professionals, and (4) are reviewed and updated periodically as appropriate. We also proposed that MCOs and PIHPs disseminate the guidelines to all affected providers and, upon request, to enrollees and potential enrollees. Finally, we specified that decisions with respect to utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply must be consistent with the guidelines.

Comment: One commenter said that §438.236 should apply to dental plans.

Response: We agree with the commenter. This section should apply to PAHPs, including dental plans, as well as to MCOs and PIHPs, and we have revised §438.236 accordingly. We note that the scope of services in the PAHP contract will determine the areas in which practice guidelines are appropriate. For example, dental guidelines would only be appropriate for plans that are responsible for providing dental services. Likewise, a clinical practice guideline is incompatible with transportation services, making this section inapplicable to transportation PAHPs.

Comment: One commenter recommended that the regulation require MCOs and PIHPs to use practice guidelines developed and/or endorsed by the American Academy of Pediatrics.

Response: We are not specifying what guidelines MCOs and PIHPs must adopt but rather are establishing criteria to be used by MCOs and PIHPs in adopting guidelines.

Comment: Several commenters objected to the requirement that MCOs and PIHPs adopt practice guidelines. One commenter said that guideline adoption should not be required because nationally accepted standards are not available for all clinical areas, for example, for rehabilitative mental health services. Another commenter objected to this provision because he believes that to require use of clinical practice guidelines substitutes the judgment of CMS, the States, and MCOs and PIHPs for the judgment of health care professionals. Other commenters supported the provision but suggested that reference be made to HIV/AIDS guidelines or that the provision also require the use of clinical review criteria that are directed specifically to meeting the needs of at-risk populations.

Response: We continue to believe that States should require MCOs, PIHPs, and

PAHPs (where appropriate) to adopt clinical practice guidelines in order to ensure the highest quality of care to enrollees. We are aware that clinical practice guidelines are not available for all areas of clinical practice. However, we believe that it is important to promote the use of guidelines based on clinical evidence. Guidelines are being developed by a variety of organizations in a variety of areas and will increasingly become available for use. This is why we have set criteria for MCOs, PIHPs, and PAHPs to use when adopting guidelines rather than specifying particular guidelines to be used. We do not agree that requiring the use of practice guidelines substitutes the judgement of CMS, States, or health plans for the judgement of health care professionals. Rather, guidelines assist health care professionals to apply the best evidenced-based practice to clinical care. Guidelines are developed to assist the health care professional, not to dictate a specific course of action. We require that MCOs, PIHPs, and PAHPs consult with their contracting health care professionals when adopting practice guidelines to ensure that the health care professionals have input into these decisions.

Comment: One commenter stated that the regulation should require MCOs to consult with organizations that develop practice guidelines.

Response: We do not agree that it is necessary or practical to require MCOs, PIHPs, and PAHPs to consult with organizations that develop practice guidelines. What we believe is important is that the guidelines are valid and reliable, are relevant to the enrollee population, are adopted in consultation with the contracting health care providers, and are reviewed and updated periodically to ensure that they continue to reflect the most recent evidence. Therefore, these are the criteria we specify in the regulation for MCOs, PIHPs, and PAHPs to use when adopting practice guidelines.

15. Quality assessment and performance improvement program (Proposed §438.240)

This section set forth the State's responsibility to ensure that each MCO and PIHP with which it contracts have in place a quality assessment and performance improvement program for the services it furnishes to Medicaid enrollees. In the NPRM we proposed that States must require that each MCO and PIHP include the following basic elements in its quality assessment and performance improvement program: (1) conduct performance improvement projects, (2) have in effect mechanisms to detect both underutilization and overutilization of services, and (3) have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

In our proposed rule we specified that CMS, in consultation with States, and other stakeholders, may specify standardized quality measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs. We proposed that MCOs and PIHPs measure performance using standardized measures annually, and implement performance improvement projects that address clinical and non-clinical areas. We also proposed that States review, at least annually, the impact and effectiveness of their quality assessment and performance improvement programs.

Comment: Several commenters supported the quality assessment and performance improvement provisions.

Response: We retain the provisions in §438.240 in the final rule with certain revisions, discussed below.

Comment: One commenter supported the provision that CMS will consult with States and other stakeholders if we decide to exercise our authority to specify quality

measures or topics for performance improvement projects that we would require States to include in their contracts with MCOs.

Response: We believe it is important to include all stakeholders in any discussions that would lead to specifying performance measures or topics for performance improvement projects that we would require States to include in their contracts with MCOs and PIHPs.

Comment: Several commenters were concerned that measures identified and developed by CMS, in consultation with States and other stakeholders, would be measures that are not routinely collected nor applicable to the unique circumstances of States and MCOs/PIHPs and that the standardized performance measures would impose additional burden. The commenters suggested this requirement be removed. One commenter agreed that some standardization of performance measures is appropriate but believes the specifications for the measures should be determined by the MCO or PIHP.

Response: We hope that by including all stakeholders in discussions about performance measures that we will reach agreement about measures that are important to a wide range of stakeholders and to CMS. We recognize that each State and MCO and PIHP will have unique program circumstances and that the national measures chosen will not meet all these needs. However, the requirement to use standard measures does not preclude States, MCOs, and PIHPs from also using performance measures that they find useful. We believe we should have the ability to specify standard measures and topics for performance improvement projects to provide comparability across States for some measures and to establish national priority areas for performance improvement projects. Therefore, we retain this provision in the final rule.

Comment: Several commenters requested that we permit exceptions or deviations from the standard measures required by us.

Response: As we stated in the preamble to the proposed rule, we believe we should have the ability to specify standard measures and that we will be working in consultation with States and other stakeholders to agree upon standard measures. Policy regarding the implementation of the measures, including whether any exceptions should apply, will also be determined in consultation with stakeholders.

Comment: Several commenters disagreed with our proposal to allow CMS to specify topics for performance improvement projects. One commenter stated that States are in the best position to identify State health priorities and how to allocate their resources and suggested that this provision be removed. Several commenters encouraged us to defer to States in determining the number and type of studies to be performed. One commenter agreed that the identification of standard performance improvement project topics is appropriate but believes that the intervention and measurement specifications should be left up to the MCOs/PIHPs.

Response: As stated in the preamble of the August 2001 proposed rule, we believe that as the art of quality improvement and measurement advances, we should have the ability to specify standard measures and topics for performance improvement projects. We retain this provision in the final rule. As in the proposed rule, in the final rule, we do not specify the number or types of quality improvement projects nor do we specify improvement interventions that MCOs and PIHPs must implement.

Comment: Several commenters expressed concern that requiring performance improvement projects to achieve demonstrable and sustained improvement is not always

feasible. Commenters said that this requirement could have a negative impact on quality improvement activities because it may impact the willingness of MCOs and PIHPs to take on difficult projects. One commenter suggested that the language in this section be changed to reflect that these projects have the goal of achieving demonstrable and sustained improvement as opposed to requiring the projects to achieve this improvement. Another commenter suggested deeming MCOs/PIHPs as having satisfied the quality assurance requirements found in this subpart if the MCO or PIHP is accredited by a private accreditation organization.

Response: We agree with the commenters that achieving demonstrable improvement is not always feasible. We have revised §438.240(b)(1) to require that performance improvement projects be designed to achieve significant improvement sustained over time. This language is consistent with Medicare requirements that define demonstrable improvement as “significant improvement sustained over time.” We plan to address deeming of MCO and PIHP quality initiatives in the EQR final rule.

Comment: One commenter suggested that we allow States discretion to require demonstrable improvement or not.

Response: As indicated in the response to the previous comment, we are no longer requiring that performance improvement projects achieve demonstrable improvement. We are requiring that these projects be designed to achieve significant improvement sustained over time. States will have the discretion to define what is to be considered significant improvement.

Comment: Many commenters argued that MCOs and PIHPs should be required to meet minimum performance levels established by the States as part of their quality

assessment and performance improvement program. The commenters recommended that this requirement be added under §438.240(b). One commenter supported that we did not propose to require MCOs and PIHPs to meet minimum performance standards. The commenter argued that it is difficult to identify reasonable performance levels when taking into consideration the variation of local conditions, beneficiaries, and unique program characteristics. This commenter recommended that the provision for standard quality measures be modified to allow States to recommend modification to the standards on a regional or State basis.

Response: We do not agree that we should require States to establish minimum performance levels that MCOs and PIHPs must meet as an element of the quality assessment and improvement program. States have the option to establish such levels, whether they are State standards or regional standards. We agree that performance measures should be included as an element of the quality assessment and performance improvement program. This was our original intent. We have changed §438.240(b)(2) to add calculation of performance measures as a basic element of quality assessment and performance improvement programs.

Comment: One commenter suggested that States require that the information obtained from assessments of underutilization and overutilization and of the quality and appropriateness of care to enrollees with special health care needs be reported by age, race, and ethnicity of Medicaid enrollees.

Response: We do not agree that this regulation should specify that information obtained on underutilization and overutilization of services or the quality and appropriateness of care furnished to enrollees with special health care needs should be

reported according to age, race, and ethnicity. We believe that each State should specify how the information should be reported based upon individual State needs.

Comment: One commenter agreed with the requirement that MCOs and PIHPs annually measure performance using standard measures required by the State and report this information to the State. The commenter believes that this provision maintains MCO and PIHP accountability while providing critical flexibility in the manner in which the requirements are carried out.

Response: We agree with the commenter and we have retained the provision in §438.240(c) of the final rule. We also take this opportunity to clarify that the State performance measures described in §438.240(c) must reflect any national performance measures that may be prescribed by the Secretary, consistent with §438.204 (c) and §438.240 (a)(2).

We also have taken the opportunity to recognize an additional approach to producing performance measures that maintains MCO and PIHP accountability while providing flexibility in the manner in which provisions at §438.240(c) pertaining to performance measurement are met. Specifically, we have been reminded of a practice used by a growing number of States in which State agencies calculate measures of the performance of their MCOs or PIHPs using encounter and claims data transmitted by the MCO or PIHP to the State. We believe this is an acceptable practice that can reduce burden on MCOs and PIHPs, especially when MCOs or PIHPs are already transmitting encounter data to the State. Therefore, we have revised §438.240(c) to indicate that there are three acceptable ways for States to obtain performance measures for each MCO and PIHP: 1) the MCO or PIHP could calculate the measures according to the States'

specifications; 2) the State could calculate the measures using encounter or similar data submitted to the State by the MCO or PIHP; and 3) a State could obtain performance measures using a combination of these two approaches. We authorize States to determine the best approach or approaches to be used in its State, recognizing that a State may decide to use different approaches for individual MCOs or PIHPs.

Comment: Several commenters agreed with the limited detail included in this regulation related to performance improvement projects. The commenters argued that the regulation sufficiently describes Federal standards while allowing States and MCOs and PIHPs the flexibility to develop processes that work best to fit their programs. One commenter requested that we work with MCOs and PIHPs and other stakeholders to develop guidance related to the final regulation that will further explain our expectations for implementing performance improvement projects (for example, challenges inherent in efforts to positively affect quality of care and outcomes given eligibility status, changes of enrollees, small populations, etc.)

Response: We retain §438.240(d) in our final rule. We have developed guidance for States on implementing performance improvement projects. As part of the development of the EQR regulation, we were statutorily mandated to contract with a national accreditation organization to develop protocols to be used in EQR. We awarded a contract to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to develop these protocols. The JCAHO, as part of this effort, convened an expert panel composed of State agencies, MCOs, experts on quality improvement activities, and other stakeholders to provide us feedback on the development of the protocols. Two protocols address performance improvement projects. One protocol provides guidance on how to

conduct performance improvement projects and one provides guidance on how to validate performance improvement projects. These protocols can be found on our web site at <http://www.hcfa.gov/medicaid/mceqrhmp.htm>.

Comment: Several commenters asked us to clarify under §438.240(d)(2) what is meant by the “new information on quality of care every year” that we are requiring be reported by the MCO or PIHP on each project upon request by the State.

Response: The MCO or PIHP should provide to the State new information from performance improvement projects underway or information on projects that had been initiated since the previous annual report. For example, a project recently initiated by the MCO or PIHP may only be able to describe the topic selected and methodology to be used at the time of the first report. In year two, the intervention may have been implemented, but there may not yet be data to report. In year three, base line data may be collected, and in year four, there may be a repeat measurement. As projects progress, different information will be available to report.

Comment: Many commenters argued that our final rule should include more specific requirements related to performance improvement projects that include more specificity such as (1) that the MCOs/PIHPs include objective, clearly and unambiguously defined measures based on current clinical knowledge or health services research (2) that the measures measure outcomes such as change in health status, functional status, enrollees satisfaction, or proxies of these outcomes, and (3) that over time, MCOs/PIHPs vary projects to focus on a full spectrum of services rather than repeatedly monitoring areas that are easy to measure and improve. One commenter was concerned that the lack of specificity in the NPRM will result in MCOs and PIHPs developing quality measures that

may be irrelevant to patient care and projects that may not protect patients. Another commenter was concerned that the lack of specificity relieves States and MCOs from developing and monitoring performance measures for specific conditions such as mental illness and other severe disabilities.

Response: We do not agree that this regulation should provide more detail on performance improvement projects or on the indicators used to measure performance. We believe the final regulation creates a balance between an appropriate amount of detail needed to ensure that States implement interventions to improve quality, while at the same time, provides States with the flexibility to determine the measures and levels they want to require of their contracting MCOs and PIHPs. We believe that States and MCOs and PIHPs will use performance measures and performance improvement projects that reflect important areas. These activities are costly and time-consuming and we believe that States and MCOs/PIHPs will target the investments in financial and staffing resources required for these activities to topics that will benefit from program improvement.

Section 438.240 requires, as a basic element of a quality assessment and performance improvement program, that MCOs and PIHPs have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. This includes beneficiaries with conditions such as mental illness and other severe disabilities.

Comment: Many commenters argued that MCOs and PHPs should be required to conduct performance improvement projects on topics specified by the State and that MCOs and PIHPs should be required to participate in at least one statewide project. The commenters recommended that we incorporate these requirements in our final rule.

Response: We do not agree that this rule should require that States have their MCOs and PIHPs participate in statewide projects. We reserve the right to set performance improvement project topics in the future as specified in §438.240(a)(2). A State, at its discretion, however, may choose to specify topics for MCOs or PIHPs improvement projects or to mandate participation in statewide projects.

Comment: One commenter encouraged us to recognize the long-term nature of quality initiatives, that improvement in quality is incremental. The commenter was concerned that the short-term commitment to initiatives that is usually the perspective of States does not provide a paradigm for studying and understanding what works in managed care. The commenter argued that quality initiatives should not change capriciously from year to year.

Response: We agree with the commenter and acknowledge that quality improvement initiatives need a sufficient amount of time to be implemented and for findings to be determined. We do not prescribe the duration in which performance improvement projects must be completed. We only require that a project be completed in a reasonable time period and that information be provided on the project's progress annually.

Comment: Several commenters asked for clarification on how the program review by States will be coordinated with the EQR regulations. Several commenter suggested that we coordinate these efforts to avoid duplication of efforts. For example, one commenter suggested that we permit MCOs and PIHPs that are certified by an accreditation agency or who are reviewed by another State agency to be exempt from Medicaid reviews and EQR. One commenter suggested that we provide a cross reference to the EQR regulation and that

we provide States sufficient discretion to define and modify their external review activities. Another commenter suggested that we amend the regulation to allow a State to use the EQR to meet the program review by the State requirements under §438.240(e).

Response: States at their option may use EQR findings to meet the program review requirements under §438.240(e)(1). The final EQR rule addresses the circumstances under which an MCO or PIHP may be exempt from quality initiatives and what types of quality initiatives we consider to be EQR activities. We are not providing a cross reference to the EQR provisions or amending this rule to stipulate that EQR can be used to meet this requirement. We are providing States with the flexibility to decide if they want to use EQR or some other activity to meet these requirements.

Comment: One commenter agreed with the requirement that States review the MCO's and PIHP's performance on standard measures on which MCOs and PIHPs are required to report.

Response: In the final rule, we retain §438.240(e)(i) in proposed.

16. Health information systems (Proposed §438.242)

Section 1932(c)(1)(iii) of the Act requires States that contract with MCOs to develop a quality assessment and improvement strategy that includes procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees. It also provides that MCOs provide quality assurance data to the State using the data and information set specified by the Secretary for the Medicare+Choice program or other data specified by the Secretary in consultation with States. Section 438.242 proposed that States require that MCOs and PIHPs have health information systems

sufficient to provide data to States and CMS.

Paragraph (a) required that States must ensure that MCOs and PIHPs maintain data systems that collect, analyze, integrate, and report data to achieve the objectives of subpart D. It required that the system must provide information on utilization, grievances, and disenrollments (other than those that result from ineligibility for Medicaid). Paragraph (b) provided that the State must require MCOs and PIHPs to collect data on enrollee and provider characteristics and on services furnished to enrollees, and to ensure the accuracy and completeness of data received from providers by (1) verifying its accuracy and completeness; (2) screening the data for completeness, logic, and consistency; and (3) collecting service information in standard formats to the extent feasible and appropriate.

Paragraph(c) required MCOs and PIHPs to make all data available, as required in this subpart, to the State and, on request, to CMS.

Comment: One commenter urged CMS to establish national data collection standards for collection of encounter data, EPSDT information, and network information by States, using standards established under the Health Insurance Portability and Accountability Act (HIPAA) where possible.

Response: We do not agree that CMS should establish national data collection standards as part of this regulation. Under HIPAA, the Secretary is establishing standards for the electronic transfer of health data, including encounter data. The HIPAA regulations also specify the entities to which the standards apply. Medicaid MCOs and PIHPs, as well as State Medicaid agencies, will need to comply with the HIPAA regulations to the extent they apply.

Comment: One commenter noted that MCO and PIHPs can only supply data to

States to the extent they are provided data by providers. This commenter suggested that this regulation require that providers give data to health plans.

Response: This regulation is directed to States and, by placing requirements on States for their contracts with MCOs, PIHPs, PAHPs, and PCCMs, on these other entities. The regulation does not address the relationships of MCOs and PIHPs and their providers. Therefore, we are not including a provision to require data reporting by providers.

Comment: One commenter noted that it is important for States to negotiate price discounts with hardware and software vendors that can be passed on to providers and to develop guidance materials for practices preparing to install hardware and software.

Response: States are in the best position to identify means to assist providers with the electronic submission of data. We do not believe that this issue should be addressed in Federal regulations. We revised §438.242(a) by adding the words “and appeals” after “grievances”. This change was made to be consistent with §438.416, which requires States to review information collected by MCOs and PIHPs as part of the State quality strategy.

