

Memorandum

Re: Final Medicaid Managed Care Rules, Medicaid Managed Care Quality Assessment and Performance Improvement, Subpart D
Prepared by Lourdes A. Rivera
April 6, 2001

Below is a review of the changes contained in the quality assessment and performance improvement provisions of the final with comment period regulations. This memo summarizes the proposed rules and notes the changes that have been made. It does not present a full discussion of the statute and proposed regulations. For a more full explanation of the proposed rules and NHeLP=s suggestions concerning each proposed rule, see *Health Advocate* (No. 194, Fall 1998) and NHeLP

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s Analysis of HCFA BBA Proposed Rules on Medicaid Managed Care (Nov. 9, 1998),
<http://www.healthlaw.org/pubs/BBAregrs/BBAmmtoc.html>

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For a similar discussion of the statute, see
Health Advocate
No. 190 (Fall 1997).

In these final regulations, subpart D was changed significantly. The specific changes are discussed below. Overall, much more detail has been added to the final rules. Also, in the proposed rules, the designation for this subpart was ' 438.300 *et seq.* The designation under the final rules with comment is

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HCFA indicates that this subpart implements 42 U.S.C. ' 1396u-2(c)(1) of the Medicaid Act. This

provision requires State Medicaid agencies to implement a quality assessment and improvement strategy which includes access standards that ensure continuity of care and adequate primary care and specialized services capacity; examination of other aspects of care and services related to quality improvement (such as grievance procedures, marketing and information standards); procedures to monitor the quality and appropriateness of care; and regular and periodic review of the strategy.

The statute mandates that the standards developed under this provision be consistent with standards established by the Secretary of HHS as of August 1, 1998. However, standards developed by the Secretary are not to preempt more stringent standards that States establish. Guidelines applied to Medicaid managed care programs under 1915(b) waivers are to apply until the standards established by the Secretary become effective. *Id.* at ' 1396u-2(c)(1)(B).

The statute further requires the Secretary to monitor State development and implementation of quality assessment and improvement strategies and to consult with States in developing these standards. In response to comments indicating the belief that the proposed rules were too prescriptive, HCFA noted in the preamble that they consulted with States and beneficiaries in finalizing the rules. HCFA concluded that these important protections reflect what the agency believes to be Congressional intent in enacting quality and beneficiary protections. HCFA also sought to include aspects of the Consumer Bill of Rights, where legal authority permitted inclusion. As a result of this process, HCFA included many of the changes that were suggested by comments to the proposed rules and noted that the final standards are consistent with what is used throughout the health care industry. 66 Fed. Reg. at 6295. Moreover, HCFA makes the quality rules as consistent as appropriate to those applied to Medicare+Choice plans. 66 Fed. Reg. at 6297.

In the final rule, HCFA extends these standards to PHPs as well as MCOs, because the concerns that prompted Congress to impose quality requirements on MCOs equally apply to PHPs, namely financial risk. 66 Fed. Reg. at 6296.

Because of the delay by the Bush Administration of the effective date, individuals with special needs and pregnant women are particularly affected. For example, these rules contain requirements that would ensure that these individuals are identified, screened, and assessed soon after enrollment and that a treatment plan be developed to meet individual=s needs. The rules also make clear the States

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responsibility for drafting clear contracts delineating what services the MCOs and PHPs are to provide and over what services will the State retain responsibility. Currently, there is a lot of

confusion in this area, leaving many beneficiaries who need services in limbo. Finally, the rules require that individuals who are denied services receive written notices of action.

42 C.F.R. ' 438.202B State Responsibilities

This provision sets forth the State=s responsibilities in implementing its quality strategy. 66 Fed. Reg. at 6298-99. In the final rule, HCFA adds the requirement that State agencies must provide for input of beneficiaries and other stakeholders in the development of the State strategy, including by making the strategy available for public comment prior to its adoption, and must document the State strategy in writing. ' 438.202(b), (c). HCFA considers State agencies such as State Mental Health and Substance Abuse agencies, Title V Maternal and Child Health agencies, and IDEA agencies as stakeholders who should have input into the development of the strategy. 66 Fed. Reg. at 6318.

States also must now submit to HCFA a copy of the State=s initial strategy and of any revisions when significant changes are made.

438.202(f)(1). States also must provide regular reports to HCFA on the implementation and effectiveness of the quality assessment and performance improvement strategy at least every three years.

438.202(f)(2).

In response to comments questioning the three-year period for State review of its strategy, HCFA clarified in the preamble that the review in this provision refers to the *State=s* quality strategy, not to the actual State monitoring and review of MCOs and PHPs which is addressed elsewhere in the rules. Thus, the language was amended to require the State to *periodically* (instead of *regularly* and periodically) review its strategy and to update the strategy as often as the State considers appropriate, but at least every three years.

438.202(e).

42 C.F.R. ' 438.204 B Elements of State Quality Strategies

This section sets forth the minimum elements of a State quality strategy, including contract provisions, for assessing the quality and appropriateness of care and services provided. 66 Fed. Reg. at 6299-6300.

A revised paragraph (b) requires that State procedures for assessing the quality and appropriateness of care and services furnished to MCO and PHP Medicaid enrollees include procedures that 1) identify enrollees with special needs; and 2) assess the quality and appropriateness of care furnished to these enrollees. ' 438.204(b)(i), (ii). In addition, States must also have procedures to identify the race, ethnicity, and primary language of each Medicaid enrollee and provide this information to the MCOs and PHPs at the time of enrollment. ' 438.204(b)(iii). HCFA added this latter provision because it believes that in order for MCOs and PHPs

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to effectively address cultural competency, they all must have basic information on the cultural characteristics of their Medicaid enrollees.

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66 Fed. Reg. at 6300.

States also must include in their strategy any performance measures and levels prescribed by HCFA consistent with the BBA. ' 438.204(c). HCFA adopted this provision in response to comments suggesting that specific performance measures be included in the rules. HCFA declined this recommendation stating that performance measures and standards change over time and it is important that the most current and useful measures can be adopted quickly. In

438.240(c)(2)(ii)(A), HCFA also imposes an obligation on States to require contracting MCOs and PHPs to meet these specific performance levels. 66 Fed. Reg. at 6297.

HCFA refused to adopt recommendations that it require Aannual@ audits of MCOs for compliance with quality standards; monitoring of grievances and logs of calls to beneficiary hotlines; and medical record reviews in certain circumstances. HCFA explained that while

States may choose to conduct annual audits,

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such audits would not relieve States of their ongoing responsibility to

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MCOs and PHPs to ensure compliance

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Further, States are in the best position to determine how they will do this. 66 Fed. Reg. at 6299-6300. With respect to the grievances, HCFA believes that the requirement in

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438.416(d) requiring MCOs and PHPs to submit summaries of their handling of grievances to the States sufficiently addresses the concern. 66 Fed. Reg. at 6300. Since HCFA does not require States to have

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it does not feel as if it can require monitoring of hotline logs. HCFA also does not believe that it should require States to review any specific medical records, but rather it prefers to leave this decision to the State in the context of a State

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s overall quality strategy. 66 Fed. Reg. at 6300.

42 C.F.R. ' 438.206 B Availability of Services [\[2\]](#)

This provision corresponds with 42 U.S.C. ' 1396u-2(c)(1)(A)(i) which requires each State to develop and implement access to care standards as part of its quality improvement strategy. 66 Fed. Reg. at 6300-01.

Out-of-Network Medicaid Services

With respect to services that are available under the State plan, but not included in the MCO or

PHP contract, HCFA amended the language to clarify that the State does not have case management responsibilities (i.e. by Arranging@) for services not available from the health plan, but that it must make the service available from other sources. 66 Fed. Reg. at 6301-02. In the preamble, HCFA also emphasizes that its intent in promulgating this rule was to ensure that enrollees in managed care have access to covered services under the State plan, but not included in the plan contract, and that the primary duty to inform beneficiaries rests with the State; however, the State may delegate this responsibility to the MCO or PHP. 66 Fed. Reg. at 6301.

To address concerns raised about the inability to obtain appropriate care within the plan network, HCFA added the requirement that MCOs and PHPs must adequately and timely cover services out-of-network for as long as the plans are unable to provide necessary medical services covered under the contract. ' 438.206(d)(5); 66 Fed. Reg. at 6303. HCFA intends this provision to extend to the inability to provide covered medically necessary services that are related, such as Cesarean section and tubal ligation, when needed to be performed at the same time. 66 Fed. Reg. at 6303. Further, HCFA requires in the new rule that the out-of-plan access does not result in greater costs to the enrollee. 438.206(d)(8).

Provider Network Capacity

HCFA has added Apersons with special health-care needs@ to the list of anticipated Medicaid enrollees that MCOs and PHPs must pay particular attention to in establishing and maintaining its provider network.

438.206(d)(1)(i). MCOs and PHPs also must now consider provider

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in establishing networks and in expanding its services area.

438.206(d)(1)(iii), (d)(4). These changes were made in response to comments requesting that MCOs make available providers experienced in treating conditions, such as HIV/AIDS, as part

of their networks or through other arrangements. 66 Fed. Reg. at 6302, 6303. However, HCFA declined to specify the types of specialists or specific types or numbers of providers that must be included in the plan network, the level of experience needed by providers to treat particular conditions, or particular standards that specify maximum enrollee-to-provider ratios.

Id

. at 6302, 6304.

Second Opinions

In response to a recommendation that enrollees have access to a second opinion upon receiving an adverse decision, HCFA implemented new ' 438.206(d)(3). This provision requires that enrollees be provided a second opinion at the enrollee

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s request, not just in the case of an adverse action, and at no cost to the enrollee. However, HCFA did not agree that an unbiased opinion could be obtained only from an out-of-network provider. Thus, MCOs and PHPs can provide the second opinion from an in-network provider. 66 Fed. Reg. at 6306. Note, second opinions are also added in

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438.100 which concerns enrollee rights.

Women's Health Specialists

Section 438.206(d)(2) mandates direct access to women=s health specialists for female enrollees for covered women =s routine and preventive care. HCFA states that this provision was proposed consistent with 42 U.S.C.

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1396u-2(c)(1)(A)(i), which requires States to develop standards for access to care

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and with the Consumer Bill of Rights and Responsibilities (CBRR) issued by the President

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s Advisory Commission on Consumer Protection and Quality in the Health Care Industry in November 1997. 66 Fed. Reg. at 6305, 6306. HCFA amended the language to make clear that direct access to women

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s health specialists cannot be fulfilled merely by providing the opportunity to select a women
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s health specialist as a primary care provider. This requirement is in addition to the designated
source of primary care, if that source is not a women

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s health specialist.
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438.206(d)(2); 66 Fed. Reg. at 6306. HCFA also notes that this provision means that women
should have access to any women

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s health specialist within the network, unless the network providers are not accepting new
enrollees or there are other network restrictions based on the enrollees choice of primary care
provider (i.e. primary care provider can refer only to specialists within his/her subnetwork). 66
Fed. Reg. at 6305. However, women must be informed of the consequences of choosing such a
primary care provider at the time of enrollment.

Id

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HCFA states clearly that it intends the women=s direct access provision to apply to minors as
well as adults and that

need to see a women Aif there is a medical
s health specialist, there should be no impediment based on age... =

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66 Fed. Reg. at 6305. HCFA also explains that

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routine and preventive services

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initial follow-up visits for services unique to women such as prenatal care, mammograms, pap
smears, and for services to treat genito-urinary conditions such as vaginal and urinary track
infections and sexually transmitted diseases.

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Notably, HCA specified

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initial follow-up visits

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as opposed to ongoing care for these health needs, and did not include in the list labor and
delivery as was requested by comments. 66 Fed. Reg. at 6305.

HCFA declined to define in the regulation the term Awomen=s health specialist,@ because
different types of health professionals may be appropriately contracting with a health plan as

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health specialists due to education or clinical experience. However, HCFA does intend for this term to include licensed health professionals with specific clinical education and training in women
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s health care, including obstetricians, gynecologists, nurse midwives, and nurse practitioners who meet State licensing requirements. 66 Fed. Reg. at 6305.

Timely Access to Services

The proposed regulations at ' 438.306(d)(5) required States to ensure that MCOs and PHPs make services available 24 hours a day, 7 days a week. At a minimum, this requirement applied to emergency and post-stabilization services and to non-emergency services that are required immediately due to unforeseen illness. *Id.* HCFA intended this provision to ensure that individuals needing home health care and other non-hospital based services receive care, when medically necessary, during non-business hours. To clarify this intent, HCFA amended the language to simply require MCOs and PHPs to ensure that services are available 24 hours a day, 7 days a week, when medically necessary.

438.206(e)(1)(iii); 66 Fed. Reg. at 6307.

Proposed ' 438.306(d)(6) required MCOs and PHPs to ensure that its providers= hours of operation are
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convenient
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to enrollees and do not discriminate against Medicaid enrollees. HCFA amended this language by moving the
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portion of the regulation to
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438.206(e)(1)(ii) . The new rule continues to require MCOs and PHPs to ensure that providers =
hours of operation are convenient for enrollees; however, what is convenient is defined by State-established methodologies and must be at least as comparable to Medicaid fee-for-service. 66 Fed. Reg. at 6307, 6308. HCFA kept the requirement that providers not discriminate against Medicaid enrollees in
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438.206(d)(7).

Language Access

HCFA eliminated the reference to the language access requirements specified at ' 438.10 (informational requirements) in the rule requiring that MCOs and PHPs ensure that services are provided in a culturally competent manner to all enrollees.

Compare
proposed

438.306(e)(4)
with

438.206(e)(2). In doing so, HCFA explained that it strengthened the cultural competence requirements by adding a separate provision at

438.204 that requires States, as an element of the State quality strategy, to identify and provide MCOs and PHPs with information on race, ethnicity, and primary language spoken by each Medicaid beneficiary at the time of enrollment. In addition,

438.206(e)(2) was revised to ensure that services are provided in a culturally competent manner to all enrollees, including, HCFA says, to those with limited English proficiency and diverse cultural and ethnic backgrounds. HCFA also requires in final

438.10(b) that States, MCOs, PHPs and PCCMs make interpreter services available to meet the needs of all enrollees. 66 Fed. Reg. at 6312.

While HCFA declined to provide a definition of Acultural competency@ in the text of the regulations, as many comments requested, it offered the following as guidance which States may use in developing their own definition:

Cultural competency in health care is a set of attitudes, skills, behaviors, and policies that enable organizations and individuals to work effectively in cross-cultural situations. It reflects an understanding of the importance of acquiring and using knowledge of the unique health-related beliefs, attitudes, practices, and communication patterns of beneficiaries and their families to improve services, enhance beneficiary understanding of programs, increase community participation, and eliminate disparities in health status among diverse population groups.

66 Fed. Reg. at 6312.

Specific Access Standards

HCFA did not adopt suggestions to specify geographic access standards (66 Fed. Reg. at 6304) or timeliness standards (*Id.* at 6307-08). It also was not more specific with respect to physical accessibility of locations for enrollees with disabilities, stating that other provisions adequately address issues of physical access and composition of provider networks. 66 Fed. Reg. at 6304-05.

' 438.207 B Assurances of Adequate Capacity and Services

Proposed ' 438.110 was drafted under the authority of 42 U.S.C. '1396u-2(b)(5) to require MCOs to provide adequate assurances that the MCOs have the capacity to serve the expected enrollment in its service area. Specifically, Congress specifies that these assurances must demonstrate that each MCO has an appropriate range of services, and a sufficient number, mix and geographic distribution of providers. 66 Fed. Reg. at 6283-84. HCFA interpreted

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to require MCOs to submit to the State and to HCFA documentation, as determined by the State, that addressed the State

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s standards for access to care outlined in proposed

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438.306 (redesignated as

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438.206). In addition, MCO submission of documentation and State certification was to occur at least every two years and at the time the MCO enters into a new contract with the State or when there has been significant change in the MCO

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s delivery network or enrollee population. 66 Fed. Reg. at 6283.

Because proposed ' 438.110 was closely related to proposed ' 438.306 the two were redesignated as " 438.207 and 438.206, respectively, so that they can be read and applied together. Specifically, the assurances that must be provided under

438.207 must document how MCOs are addressing the access standards delineated in

438.206. 66 Fed. Reg. at 6283. HCFA also clarified that while proposed

438.306 was meant to address the substantive requirements to ensure availability of services, proposed

438.110 was to address the procedural requirements for submitting assurances of adequate capacity. 66 Fed. Reg. at 6284. Thus, HCFA did not include suggestions to include standards addressing particular services or populations in final

438.207. Instead, HCFA addressed concerns about pregnant women and persons with special needs in

438.206. However, HCFA did not include access standards to address issues such as lack of family planning services within an MCO and how those services should be made available without additional burden on the enrollee. HCFA said that States are free to address this and other issues that were raised. 66 Fed. Reg. at 6284.

Paragraph (a) of the proposed rule was revised to no longer require routine submission of documentation to HCFA, as well as to the States. Instead, MCOs are to submit the documentation to the States who, in turn, are required only to certify to HCFA that MCOs have adequate capacity and services. *Compare* proposed ' 438.110(a), (d) *with* ' 438.207(a), (d). Even though the statute requires that MCOs provide adequate assurances to

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the State and the Secretary,

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HCFA amended the language to address concerns that the proposed rule would interfere with the State

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s monitoring role and that submission of documentation to HCFA as well would constitute a significant administrative burden on MCOs. 66 Fed. Reg. at 6285.

Final ' 438.207(b) requires submission of documentation to the State in a format specified by the State and acceptable to HCFA. While HCFA is not specifying the type of format that must be

used, it stated that it will provide more formal guidance on acceptable formats once HCFA gains more experience in implementing this provision. 66 Fed. Reg. at 6285.

In response to comments questioning HCFA's authority to require sufficient capacity related to specialists services, HCFA responded that although 42 U.S.C.

1396u-2(b)(5) refers expressly only to preventive and primary care services, it also requires assurances of

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capacity to serve the expected enrollment.

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Presumably, HCFA says, this includes those enrollees who need specialty services. In addition, while this section specifies expressly that these assurances should

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includ[e] assurances with respect to preventive and primary care, this does not mean that assurances about other services are not necessary.

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HCFA also points to the clause discussing preventive and primary care at

1396u-2(b)(5)(A) as referencing

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an appropriate range of services

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and to

1396u-2(b)(5)(B) which requires

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a sufficient ... mix of providers of services.

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Under the interpretation of its authority of ' 1396u-2(b)(5), HCFA has required assurances of specialty services as well. ' 438.207(b)(1); 66 Fed. Reg. at 6286.

One comment requested clarification of the term Amix@ in the requirement AMaintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the area

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(proposed

428.110(b)(2)), HCFA responded that it interprets this term to refer to provider types, such as types of specialists. 66 Fed. Reg. at 6286. This language was maintained in the final rule.

438.207(b)(2). However, HCFA further explained that States will have to review documentation submitted by MCOs to ensure that each MCO also meets access provisions, including provision of services in a culturally competent manner.

438.206(e)(2).

Proposed ' 438.110(c) provided timeframes for submission of required documentation: 1) at least every two years; 2) at the time an MCO enters into or renews a contract with the State; and 3) at any time the State determines there has been a significant change in the MCOs delivery network or enrollee population. In response to concerns that the two-year time period is too long and may not sufficiently protect beneficiaries and in response to comments that some States may be reviewing capacity more frequently, HCFA revised the rule to require submission of documentation on an annual basis.

' 438.207(c). HCFA maintains the requirement that documentation be submitted when health plans enter into contracts with States.

' 438.207(c)(1). However, instead of requiring documentation upon renewal, the new language requires documentation when there has been a

significant change (as defined by the State) in the MCO

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s operations that would affect adequate capacity and services...

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438.207(c)(2). The changes triggering the requirement include: (1) significant changes in services or benefits; (2) an expansion or reduction of the geographic service area; (3) the enrollment of a new population; and (4) a significant change in MCO or PHP rates.

Id

; 66 Fed. Reg. at 6287.

In addition, HCFA clarified the relationship between this section and 1915(b) waiver applications. HCFA states that if there has been a significant period of time between the State=s assessment of adequate capacity at the time of waiver renewal, HCFA may ask the State to update its analysis and may request documentation from MCOs at that time. 66 Fed. Reg. at 6287.

HCFA also outlined its enforcement mechanisms should MCOs fail to demonstrate that

adequate capacity. The monitoring mechanisms include reviewing State reports and MCO and PHP documentation; interviewing representatives of the State, MCO or PHP; interviewing enrollees; reviewing provider agreements and contracts; and surveying participating providers. Enforcement mechanisms range from issuing letters and corrective action plans to imposing terms and conditions under waiver programs, to conducting regular on-site monitoring reviews, and to withholding FFP under final ' 438.802(c). HCFA states that its goal is to work with States to resolve problems and take appropriate action. 66 Fed. Reg. at 6287.

HCFA received comments suggesting that an MCO should be granted Awaiver@ of the requirement to document adequate capacity under this section if the MCO has made a

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to solicit providers to participate in the plan

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s network. HCFA responded that in setting access standards, States have the flexibility to take into account a lack of provider types in certain geographic areas; limitations on the number of certain providers nationally, and other factors that may make it difficult for MCOs to always be able to construct a provider network that will address the health care needs of its enrollees. 66 Fed. Reg. at 6288. As a result of this concern, HCFA requires in new

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438.207(b)(4) that MCOs have policies and practices to address unanticipated need for providers with particular types of experience; and the unanticipated limitation of the availability of such providers. 66 Fed. Reg. at 6288. HCFA also requires in

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438.206(d)(5) MCOs to permit enrollees to access out-of-network providers if the MCO

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s network is unable to meet an enrollee

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s needs. 66 Fed. Reg. at 6288.

' 438.208 -- Coordination and Continuity of Care

Proposed ' 438.308 set forth requirements to ensure that States require MCOs and PHPs to maintain continuity and coordination of care for its enrollees. Significant changes were made in the content and organization, including the move of provisions in proposed

438.306(e)(2), (3) pertaining to initial health assessment, and pregnancy and complex and serious medical conditions to this section.

Screenings and Assessments

The proposed regulations required States to ensure that MCOs provide initial assessments of each enrollee within 90 days of enrollment, and within shorter periods of time for pregnant women and enrollees with complex and serious medical conditions. Proposed ' 438.306(e)(2). These requirements are amended and re-designated in

438.208. These rules are applicable to PHPs to the extent that they are applicable to the services furnished by the PHP. However, States must ensure that all Medicaid managed care enrollees are screened.

438.8, 438.208(a)(2); 66 Fed. Reg. at 6310.

Identification: In the final rule, HCFA identifies a more extensive list of individuals which must be identified as Aat risk@ in order to receive initial screens, follow-up assessments and treatment. These include persons with special health care needs, children under age 2, and other enrollees known by the State to be pregnant or to have special health care needs. Persons with special health care needs, in turn, include SSI beneficiaries; children in Title IV-E foster care; enrollees in relevant, State-established, risk adjusted, higher cost payment categories; and any other category of recipients identified by HCFA.

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HCFA also places the burden on the States to identify these individuals to the health plans upon the individuals

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enrollment.

438.208(b); 66 Fed. Reg. at 6308.

Screens v. Assessments: In the final rule, HCFA deletes the term Ainitial assessment@ as ambiguous and differentiates between the terms

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comprehensive health assessment.

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An initial screen, according to HCFA, may take the form of a phone call, mailed questionnaire, home visit or physical examination. The initial screen must be sufficient to identify individuals with special needs and to identify languages, TTY requirements, and needs for accessible medical facilities and/or transportation services. A comprehensive health assessment includes a physical examination by an MCO or PHP provider. 66 Fed. Reg. at 6309.

Timeframes: HCFA also revised the timeframes for screening and comprehensive assessment. Under the proposed rule, MCOs were required to provide Ainitial assessments@ (i.e. screens) to each enrollee within 90 days of enrollment and within shorter time periods as established by the State to pregnant women and persons with complex and serious medical conditions. For pregnant women and persons with these special needs, the MCO was to have A
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identification and (for persons with special needs) assessment of conditions and identification of appropriate medical procedures for monitoring and treatment of these conditions.

438.306(e)(2), (3).

Under the final rules, each MCO and PHP must perform screening within 30 days of the enrollee being identified as Aat risk@ by the State. For all other enrollees, the MCO or PHP must provide a screen within 90 days of enrollment to determine whether the enrollees are pregnant or have special health care needs and have ongoing mechanisms to identify enrollees who develop these conditions. For any screened enrollee identified as being pregnant or to have special needs, the MCO or PHP is to provide a comprehensive health assessment as expeditiously as the health condition requires, but no later than 30 days from the date of the identification. Except that enrollees identified by the State as being a child under age 2, pregnant, or to have special health care needs, or for enrollees who self-identify as being pregnant or to have special health needs, the health plan is to provide a comprehensive health assessment within 30 days without the need of the initial screen.

438.208(d), (e).

In amending these time frames, HCFA noted that MCOs and PHPs should use their Abest

efforts to meet these screening requirements. HCFA recognizes that health plans may not be able to achieve 100 percent compliance through no fault of their own

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i.e. some enrollees will not or cannot cooperate in obtaining screens and assessments. However, HCFA emphasized that this does not relieve MCOs and PHPs of their obligation to screen each enrollee. Specifically, HCFA expects the health plans to follow-up on unsuccessful attempts to contact enrollees and to document attempts to screen and assess individual enrollees. 66 Fed. Reg. at 6309.

For enrollees for whom current health information is available (i.e. enrollees under the care of MCO network providers or enrollees maintaining the same primary care provider when enrolling in a different MCO), the screen could be considered to have been performed. However, the health plan should document the reason why a screen is not necessary in the enrollee's medical record. 66 Fed. Reg. at 6309.

In response to a request that proposed ' 438.306(e)(3) be amended to require MCOs to provide EPSDT screens and mandated services, HCFA responded that current regulations require EPSDT screens. Therefore, inclusion of such a requirement in the BBA regulations would be duplicative. 66 Fed. Reg. 6311.

Treatment Planning

Proposed ' 438.306(e)(3) set forth rules on the identification of pregnant women and persons with complex and serious medical conditions and for the development and implementation of treatment plans that are appropriate for the conditions identified, specify an adequate number of direct access visits to specialists, and are updated periodically by the physician responsible for the overall coordination of the enrollee's care.

With respect to direct access to specialists, HCFA amends the language from A specifies an adequate number of direct access visits to specialists as required by the treatment plan

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to

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Specifies a standing referral or an adequate number of direct access visits to specialists.

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Compare
proposed

438.306(e)3(iii)

with
final

438.208(f)(3). In proposing and in finalizing this rule, HCFA indicated that its intent was to ensure that enrollees with special health care needs be permitted a sufficient number of direct access visits to specialists as required by the treatment plan without needing to obtain numerous authorizations from their primary care provider. HCFA sees this requirement as necessary to meet the access standards at 42 U.S.C.

1396u-2(1)(A)(i). 66 Fed. Reg. at 6310. The amendment was made in recognition of varying MCO and PHP practices. 66 Fed. Reg. at 6310. HCFA also States that it expects the treatment plan to specify the specialist(s) to whom the enrollee has direct access. However, HCFA did not believe it necessary to require in the regulations that the treatment plan specify the actual names of the specialists. 66 Fed. Reg. at 6312.

The rule retains the requirement that the treatment plan be time specific and updated periodically to determine the need for continued direct access visits. ' 438.208(f)(2); 66 Fed. Reg. at 6310. The revised language adds that the treatment plan should ensure appropriate coordination of care among providers; be developed with enrollee participation; and ensure periodic reassessment of each enrollee as his or her health condition requires.

438.208(f)(3)-(4); 66 Fed. Reg. at 6310-11. In addition, MCOs and PHPs are to use
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appropriate health care professionals
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to perform assessments and to develop, implement and update treatment plans.

438.206(g); 66 Fed. Reg. at 6312.

In response to concerns about individuals with ongoing health care needs who are transitioning to managed care, HCFA added ' 438.62(b) which requires States to have a mechanism to ensure continued access to services. These requirements apply to individuals transitioning from fee-for-service to managed care, from one managed care plan to another, or from managed care back to fee-for-service. HCFA believes that this provision, along with the requirements in ' 438.208 requiring identification of persons with special needs, screening, assessments, and treatment planning, address the continuity of care concerns. 66 Fed. Reg. at 6311, 6313.

Pre-existing patient-provider relationships

HCFA rejected the comments suggesting that pregnant women and persons with special needs be permitted to continue to obtain services from providers with whom these individuals have pre-existing relationships. HCFA responded that it would be inconsistent with Congressional intent as contained in 42 U.S.C. ' 1396u-2(a)(2) where Congress specifically exempted certain categories of individuals from mandatory enrollment. As such, HCFA does not feel that it had the authority to include additional groups. Similarly, HCFA does not believe that it has the authority to require health plans to cover non-emergency services furnished by a non-plan provider. However, HCFA noted that the regulations are not intended to preempt State laws that would require continuation of care outside of the plan network. 66 Fed. Reg. at 6313.

Designation of primary care provider

HCFA refused to specify in the rule that enrollees with special needs should be able to designate specialists as their primary care providers. This is because (1) the existing evidence base regarding better health outcomes for individuals whose primary care provider is a specialist is limited; (2) it is not possible at present to specify in this regulation all the decision rules to direct when a given individual must have a specialist as a primary care provider; (3) it is not appropriate to revise the final rule with comment period to prohibit primary care systems from acting as care managers for persons with complex behavioral needs. In sum, States should have the flexibility to make these decisions. 66 Fed. Reg. at 6313-14.

On the other hand, HCFA did amend the final rule to allow individuals to designate a medical group or provider entity, instead of an individual provider, for primary care and overall coordination. Section 438.208(h) requires States to ensure that each PHP and MCO: (1) provide each enrollee with an ongoing source of primary care appropriate to his or her needs; and (2) have a mechanism to identify the person or entity formally designated as primarily responsible for coordinating the enrollee=s health care. While HCFA has added this flexibility, it urges MCOs and PHPs to make every effort to promote a relationship between an enrollee and a single primary care provider.

Primary Care and Care Coordination

Proposed ' 438.308(a), (b) were amended extensively and re-designated as ' 438.208(h). These provisions deal with the MCOs

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and PHPs

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responsibility to implement a primary care and care coordination program.

Care coordination: Several comments requested clarification on what type of care coordination model HCFA was proposing in ' 438.308(a). 66 Fed. Reg. at 6314. This proposed section would have required the designation of a health care practitioner who was primarily responsible for coordinating the enrollee

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s overall health care and the specification of whether coordination was to be provided by the enrollee

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s primary care provider or by a different provider. Proposed

438.308(a). HCFA responded that its primary intent in implementing this section was to ensure that, regardless of the care coordination model, each MCO and PHP made every effort to promote a relationship between the enrollee and the primary care provider source. 66 Fed. Reg. at 6314. As such, HCFA amended the language to better reflect its intent to now read: Each MCO and each PHP must implement a coordination program that ... Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

438.208(h)(1).

Coordination of out-of-plan services: Proposed ' 438.308(b) would have required an MCO to ensure coordination of services internally and with services available from community organizations and other social programs. In revising the final rule, HCFA agreed with comments suggesting that the range of care coordination responsibilities of managed care plans are complex and varied. HCFA deleted the requirement that health plans coordinate services with community organizations and other programs in the final rule, but noted that MCOs and PHPs may still have such care coordination responsibilities, depending on their contracts with States. 66 Fed. Reg. at 6313-14. States may decide to delegate to the MCOs and PHPs their responsibilities to coordinate services as required under other regulations (e.g.,

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coordination with State health and vocational rehabilitation agencies and Title V grantees;
431.620

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with State mental health authority of mental institutions; 431.635

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with WIC). 66 Fed. Reg. at 6313-14.

However, HCFA did not eliminate all care coordination responsibilities from the regulations. MCOs and PHPs must coordinate services it provides with services the enrollee receives from any other MCO or PHP; share the results of screenings and assessments with other MCOs and PHPs so that these activities do not have to be repeated; ensure privacy protection in the process of care coordination; ensure that each provider maintains medical records that meet professional standards and that there is appropriate and confidential information sharing among providers; have in effect procedures to address factors (such as lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens; and ensure that its providers have the information necessary for effective and continuous patient care and quality improvement. ' 438.208(h)(2)-(7); 66 Fed. Reg. at 6315.

Privacy and Confidentiality

Proposed ' 438.308(c)(2) would have required an appropriate and confidential exchange of information among providers. In drafting this rule, it was HCFA =s intent to ensure that MCOs and PHPs and their providers have the information necessary for effective and continuous patient care and quality improvement. HCFA explains that it did not intend for this provision to require informed consent by beneficiaries or to supersede relevant State law governing the exchange of information between providers. To clarify its intent, HCFA amended the final language in

438.208(h)(7) to specify that each MCO and PHP must ensure that its providers have the information necessary for effective and continuous patient care and quality improvement

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consistent with the confidentiality and accuracy requirements of

438.224 and the information requirements of

438.242.

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MCOs and PHPs also must ensure privacy protection, consistent with

438.242, in the care coordination programs discussed above. Based on these changes, HCFA

did not feel the need to define the term

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confidential

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in this provision. 66 Fed. Reg. at 6315.

Enrollee Participation

Proposed ' 438.308(d) would have required MCOs and PHPs to have procedures to ensure enrollee participation. Specifically, procedures were required to (1) inform enrollees of specific conditions that require follow-up and, if appropriate, provide training in self-care; and (2) deal with factors that hinder enrollee compliance with prescribed treatments or regimens.

Id

. HCFA was persuaded by the comments that some of the language of the proposed rules was unclear and subjective. In addition, HCFA noted that potentially all conditions requiring a provider visit require some degree of follow-up. HCFA therefore amended the final language to require only that MCOs and PHPs have in effect procedures to

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address factors (such as lack of transportation) that hinder enrollee adherence to prescribed treatment or regimens.

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438.208(h)(6); 66 Fed. Reg. at 6415.

' 438.210 B Coverage and Authorization of Services

HCFA also extensively revised proposed ' 438.310 and redesignated the section as ' 438.210. The proposed rules set forth requirements to ensure that each contract with an MCO or PHP identify all services offered under the contract and follow written policies and procedures for processing requests for services in a manner that ensures access to these services. In addition, the proposed rules would have ensured that utilization management procedures were not structured in a manner that is detrimental to enrollees.

This section, according to HCFA, implements 42 U.S.C. ' 1396u-2(b)(1) of the Medicaid Act.

Coverage

HCFA revised paragraph (a) to clarify the contract requirements. Specifically, subparagraph (a)(1) requires each contract to identify, define and specify each service that the MCO or PHP is required to offer. The proposed rule would have required that in addition to specifying each service, the contract would specify the amount, duration and scope of each service. Proposed ' 438.310(a)(1). In response to comments indicating that specifying the amount, duration and scope of each service would be unreasonable and would make the contract too extensive; create unintended exclusions; and not allow for consideration of patients

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specific needs, HCFA revised the language to require that services must be made available at least in the amount, duration and scope that are specified in the State plan and in the amount, duration and scope that is necessary to reasonably achieve the purpose for which the service is furnished.

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438.210(a)(1); 66 Fed. Reg. at 6316. In the preamble, HCFA notes that the intent of this provision is to ensure that enrollees receive the services that they are entitled to under the State plan, and if an MCO or PHP does not cover particular service, the State must make arrangements to ensure that enrollees are able to receive all services covered under the State plan. 66 Fed. Reg. at 6316-17.

Contracts must define Amedically necessary services@ in a manner that is no more restrictive than the State Medicaid program permits (i.e. in State law, State Medicaid plan, and other State policies and procedures). Contracts also must address the extent to which the MCO or PHP is responsible for covering services related to prevention, diagnosis, and treatment of health impairments; the ability to achieve age-appropriate growth and development; the ability to attain, maintain, or regain functional capacity. Contracts must specify that MCOs and PHPs must furnish services in accordance with these medical necessity requirements.

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438.210(a)(3)-(4).

In promulgating this revised rule, HCFA stated that A[c]lear specifications of medical necessity in the contract are critical in determining what a State is paying MCOs and PHPs to provide and, in some cases, what the State is providing outside the managed care setting for all parties in the program. @ 66 Fed. Reg. at 6317.

HCFA also notes that States retain overall responsibility for covering all services in accordance

with the State Medicaid plan, regardless of whether some or all of the services may have been contracted to an MCO or PHP. In determining whether services should be provided in individual cases, fair hearing officers are bound by the State Medicaid program coverage criteria, rather than specific criteria in the contract if the hearing officer determines that the contract is inconsistent with State Medicaid program rules. 66 Fed. Reg. at 6318.

As discussed above, the new rules contain specific guidance on what the contracts should contain with respect to medical necessity, requiring that the definition be no more restrictive than what is used in the State=s Medicaid program. However, HCFA declined to provide a standard definition of medical necessity, noting that States have always had flexibility in defining medical necessity. Moreover, A[t]he provision addressing medical necessity in no way affects any other Federal requirements governing coverage determination in the Medicaid program.

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Id

. at 6318. Nevertheless, HCFA feels that specificity in contracts will reduce the potential for MCOs and PHPs to develop definitions which are inconsistent with those developed by the State Medicaid agency.

Id

. at 6317-18. Also, HCFA will review these medical necessity contract provisions as part of its review and approval of contracts under

438.6. 66 Fed. Reg. at 6318.

HCFA also declined to refer to EPSDT requirements, stating that the regulation does not affect any of the pre-existing EPSDT regulations. To refer to the EPSDT requirements in this regulation, according to HCFA, would be redundant. 66 Fed. Reg. at 6318.

MCOs and PHPs may place appropriate limits on services based on criteria such as medical necessity or for utilization control; however, MCOs and PHPs are prohibited from arbitrarily denying or reducing the amount, duration or scope of required services solely because of the diagnosis, type of illness, or condition, and services that are furnished must be expected to achieve their purpose. ' 438.210(a)(2).

Processing of Requests

With respect to processing of requests for initial and continuing authorization of services, MCOs and PHPs must not have information requirements that are unnecessary, or unduly burdensome, for either the provider or the enrollee. ' 438.210(b). 66 Fed. Reg. at 6319 (addressing the concern that one of the reasons that enrollees do not receive services to which they are entitled is the authorization process itself).

In addition, any decision to deny a service authorization request or a decision to approve the request that is less in an amount, duration or scope than requested, must be made by a health care professional who has the appropriate clinical expertise in treating the enrollee=s condition or disease.

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438.210(b); 66 Fed. Reg. at 6319.

HCFA maintains the requirement that MCOs and PHPs must have mechanisms to ensure that review criteria must be applied consistently to authorization decisions. ' 438.210(b)(2); 66 Fed. Reg. at 6319.

Notice of Adverse Action

Contracts must provide for MCOs and PHPs to notify the requesting provider and give the enrollee written notice of any decision to deny a service authorization or to authorize a service in an amount, duration or scope that is less than requested. The notice must meet the requirements of ' 438.404. However, to ease the burden on MCOs and PHPs, notice to the provider need not be in writing. ' 438.210(c); 66 Fed. Reg. at 6319.

Timeframes for Authorization decisions

HCFA amended the proposed language in ' 438.310(d) which required that services be furnished within 14 days after the receipt of the request (and within 72 hours for urgent cases). HCFA explained that the intent was to apply the timeframes to the authorization of services and not to the furnishing of services. 66 Fed. Reg. at 6320. The final rule at

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438.210(d) and (e) makes clear that the time frames apply to the standard and expedited authorization decisions. HCFA also notes that these time frames are consistent with those in

Medicare. In addition, the time frames for standard and expedited authorizations can be extended up to an additional 14 calendar days at the request of the enrollee (or the provider in the case of standard authorization) or if the MCO or PHP justifies the extension to the State agency. 66 Fed. Reg. at 6320.

Compensation for Utilization Management Activities

HCFA has retained the requirement that compensation to utilization review entities not be structured so as to provide incentives to deny, limit, or discontinue medically necessary services. ' 438.210(f); 66 Fed. Reg. at 6320.

Structure and Operation Standards

' 483.214 B Provider Selection

Proposed ' 438.314 required State Medicaid agencies to ensure that MCOs and PHPs have written policies and procedures for the selection and retention of providers. 66 Fed. Reg. at 6320. This requirement is retained and strengthened. " 438.214(a) (requiring written policies and procedures); 438.214(b)(requiring MCOs and PHPs to follow a documented credentialing process). See

also

66 Fed. Reg. at 6321 (

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The intent of this rule was to ensure that MCOs and PHPs implement a formal selection process and, at a minimum, that the process address provider qualifications, provider discrimination, the exclusion of certain providers and additional requirements States may want to impose.

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HCFA revised this section in a number of ways. First, it changed the heading from Aestablishm

ent of provider networks

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to

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provider selection.

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Second, HCFA reorganized the section to clarify the requirements that apply to licensed independent providers (e.g., physicians) and other providers and created an exception from these rules that applies to providers who are permitted to furnish services only under the direct supervision of a physician or other provider and for hospital-based providers who provide services only incident to hospital services. ' 438.214(b)(1), (3). However, the hospital-based provider exception does not apply if the provider contracts directly with the health plan or is promoted by the health plan as being part of the provider network.

438.214(b)(3). 66 Fed. Reg. at 6320-21. HCFA noted that it did not adopt NCQA credentialing standards, as was suggested, even though the requirements in the regulations have similarities with the NCQA standards. 66 Fed. Reg. at 6321.

Third, HCFA added requirements that the initial provider credentialing application be dated and signed and that applications, updates and supporting information submitted by the applicant include an attestation of correctness and completeness of information.

Fourth, HCFA added a new requirement that specifies that MCOs and PHPs may not employ or contract with providers excluded from participation in federal health care programs. This is a clarification of the proposed rule requiring that selection criteria be based, in part, on eligibility for payment under Medicaid. Proposed ' 438.314(b)(1). HCFA made the rule more narrow by precluding only those providers who have been barred from participation in federal programs (i.e. providers convicted of fraud). This change was made in response to a comment noting that an MCO may wish to provide services through a provider in good standing who is not an eligible provider type under fee-for-service. 66 Fed. Reg. at 6322.

Finally, HCFA requires that each MCO and PHP comply with any additional State requirements. ' 438.214(e).

HCFA did not adopt the suggestion to prohibit MCOs and PHPs from removing providers from

its network without cause. While States would be permitted to adopt such a rule under ' 438.214(e), HCFA believed that MCOs and PHPs may have good reasons to remove providers without cause

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i.e. the MCO or PHP needed to decrease its provider network if beneficiary enrollment decreased. 66 Fed. Reg. at 6321. However, MCOs and PHPs must give providers written notice of the reason for the decision to remove them from the networks under

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438.12(a)(1).

HCFA also did not adopt the recommendation that MCOs not be permitted to have separate panels of providers for Medicaid and for their other lines of business. According to HCFA, this requirement would not be practical nor would it be in the best interest of beneficiaries, because some of the most successful managed care programs have employed providers with particular experience in treating Medicaid beneficiaries. HCFA also is concerned that imposing this rule would eliminate some managed care providers as an option for Medicaid enrollees. 66 Fed. Reg. at 6322.

HCFA did retain the requirement in proposed ' 438.314(b)(3) that expressly provides that selection and retention criteria could not discriminate against providers who serve high risk populations.

' 438.214(c). In doing so, HCFA states that it believes that many Medicaid beneficiaries are best served by providers who are experienced in caring for individuals with the health or social conditions that make an enrollee

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high risk,

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such as poverty, homelessness, or disrupted family situations. However, HCFA refused to provide a definition of high risk, stating that States should be free to interpret what constitutes a high risk population based on their knowledge of these groups in their State. 66 Fed. Reg. at 6321.

' 438.214 B Enrollee Information

The provisions in the proposed rules at ' 438.314 were moved to ' 438.10. In this section, HCFA

makes clear that the enrollee information requirements constitute part of the State
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s quality strategy under
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438.204.

Proposed ' 438.320 B Enrollee Rights

This section was moved to ' 438.100.

' 438.224B Confidentiality and Accuracy of Enrollee Records [\[4\]](#)

In proposing ' 438.324, HCFA intended to ensure that MCOs and PHPs would be held responsible for safeguarding the confidentiality of enrollee information. HCFA states that it did not intend to impose specific guidelines for the use and disclosure of enrollee information, due to the extensive existing federal and State laws on confidentiality and due to the confidentiality rules being promulgated under HIPAA. 66 Fed. Reg. at 6324-25. To underscore its intent not to create new technical standards, HCFA deleted sections of the proposed rule that, according to HCFA, are already covered under existing rules. However, HCFA also clarifies that MCO and PHP procedures must safeguard confidentiality of any information that identifies a particular enrollee and not only medical records, but also any other health and enrollment information maintained with respect to enrollees. ' 438.224. To address the concern about the ways in which patient information is used or disclosed, HCFA added the requirement on States to ensure that each MCO and PHP establish and implement procedures to ensure that enrollees receive, upon request, information on how MCOs and PHPs use and disclose identifiable information. ' 438.224(e). 66 Fed. Reg. at 6325-26.

Proposed ' 438.324(b)(1) would have required that original medical records be released only in accordance with Federal or State law, or court orders or subpoenas. However, as was pointed out in a comment received by HCFA, this provision would conflict with existing ' 431.306(f) which requires that when a court issues a subpoena for a case record, the Medicaid agency must inform the court of the applicable statutory provisions, policies and regulations restricting disclosure of information. 66 Fed. Reg. at 6325. HCFA also noted that should an MCO or PHP receive a request for enrollee

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s information, that typically only copies of the information would be released. HCFA explained that it was its intent that originals are to be released only in accordance with applicable laws.

To more accurately reflect this intent, HCFA deleted in the final rule at ' 438.224(c) the specific reference to court orders and subpoenas, and eliminated the provision singling out original records from other health information. HCFA also directs MCOs and PHPs to follow the requirements at Subpart F of part 431 in response to subpoenas.

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438.224; 66 Fed. Reg. at 6325.

MCOs and PHPs must abide by all Federal and State laws regarding confidentiality and disclosure and must establish and implement procedures that specify for what purposes the MCO or the PHP uses the information and to which entities outside the MCO or PHP (and for what purposes) it discloses the information. ' 438.224(b), (c). These provisions were added to more clearly define what would constitute an authorized disclosure to address the confusion created by the proposed ' 438.324(b)(2) which would have required information to be disclosed to

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authorized individuals
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only. In making these changes, HCFA deleted reference to

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authorized individual
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which could be interpreted in different ways. 66 Fed. Reg. at 6325.

Proposed ' 438.324(d) required that States ensure that health plans have procedures to ensure that enrollees have timely access to the records and information that pertain to them.

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The final language was amended to more clearly reflect HCFA

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s intent to ensure that MCOs and PHPs have orderly procedures to enable enrollee access to

his or her medical records in a timely manner. Thus, 438.224(f) requires States to ensure MCO and PHP procedures to ensure that each enrollee may request and receive a copy of his or her records and information and added a requirement that the enrollee may request that they be amended or corrected. However, HCFA declined to specify particular time lines or other requirements which may conflict with existing federal or State laws. 66 Fed. Reg. at 6326.

HCFA deleted the reference to confidentiality of minors from proposed ' 438.324. HCFA stated that its intent was not to interfere with existing Federal and State laws that address minor confidentiality and to ensure that MCOs and PHPs have procedures to protect the confidentiality of all enrollees, including minors. 66 Fed. Reg. at 6326.

' 438.226 B Enrollment and Disenrollment

There were no changes made in this section. HCFA continues to require that States ensure that each MCO and PHP comply with the enrollment and disenrollment requirements and limitations set forth in ' 438.56.

' 438.228 B Grievance Systems

In addition to continuing to require States to ensure that each MCO and PHP has in effect a grievance system that complies with Subpart F, HCFA now requires States to conduct random reviews of each PHP and MCO, its providers, and subcontractors if a State delegates the responsibility of providing notices of action to ensure that enrollees receive timely notice. ' 438.228(b). In addition, States must establish processes to review, upon enrollee request, any quality of care grievance that the MCO or PHP does not resolve to the enrollee

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s satisfaction.
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438.228(c). 66 Fed. Reg. at 6327.

' 438.230 B Subcontractual Relationships and Delegation

Proposed ' 438.330 would have required States to ensure that MCOs and PHPs entering into a contract with the State oversee and remain entirely accountable for the performance of any activity it delegates to a subcontractor. Under this provision, it would be the sole responsibility of the MCO and PHP to ensure that the delegated activity or function is performed in accordance with the contract. 66 Fed. Reg. at 6327-28. HCFA has included a new requirement that, consistent with " 438.604 and 438.606 pertaining to submission of data that must be certified, each MCO and PHP must require subcontractors to provide certifications with respect to performance of their duties under the contract and submissions that may be related to State payments. ' 438.230(b)(5). Thus, it is unnecessary to require States

to directly monitor subcontractor performance, although a State may choose to do so.

Id

. at 6328.

HCFA also refused to require public access to subcontracts, because the MCOs and PHPs are the responsible parties. However, access to such documents continue to remain subject to State disclosure policies and procedures. *Id.* at 6327.

Because of the responsibility placed directly on MCOs and PHPs, HCFA also declined the recommendation that health plans certify to the States that payments under a subcontract are sufficient for the services required. Under ' 430.230(b)(1), health plans must evaluate subcontractors = ability to perform activities before

delegation occurs. HCFA notes that the evaluation

may

include evaluation of the subcontractors

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financial stability.

66 Fed. Reg. at 6327.

HCFA revised this rule to require each MCO and PHP to formally review its subcontractors= performance according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations.

438.230(b)(3). In the proposed rule, this formal review was to be carried out at least once per year. Proposed

438.330(b)(3). HCFA made the change in response to a comment suggesting that the proposed rule was too prescriptive and overlapped with the provider credentialing requirements. HCFA explained that this provision was not intended to require annual re-credentialing once per year, but rather to hold MCOs and PHPs accountable for covered services provided through subcontracts. Thus, the new language requires the MCOs and PHPs to monitor the subcontractors

= performance on an ongoing basis, in addition to subjecting subcontracting arrangements to formal review on a periodic basis as established by the State. 66 Fed. Reg. at 6327.

HCFA also added a new ' 438.6(l) to require all subcontracts to meet the requirements of Part 438 that are appropriate to the service or activity that was delegated under the subcontract. 66 Fed. Reg. at 6328.

While declining to provide a definition of Asubcontractor@ in the regulations, HCFA states that it intends the term to include any non-employee individuals or organizations within the MCOs

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or PHPs

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network.

Id
. 6327.

HCFA notes that these provisions are consistent with the CBRR with respect to consumer choice or provider networks that are adequate to serve consumer needs and with respect to ensuring that States hold MCOs and PHPs accountable for the availability and adequacy of all covered services. *Id*. The final rules also reflect requirements contained in Medicare regulations for subcontractors. *Id*. at 6328.

Measurement and Improvement Standards

' 438.236 B Practice Guidelines

Proposed ' 438.336 required States to ensure that MCOs and PHPs develop or adopt and disseminate practice guidelines that met certain standards; that the guidelines be disseminated to providers, all enrollees, as appropriate, and to individual enrollees, upon request; and utilization management and other areas to which the guidelines apply are consistent with the guidelines.

Subparagraph (b) was revised to clarify that each MCO and PHP must adopt (and not develop) practice guidelines. ' 438.236(b). HCFA revised the language to clarify that it did not intend each MCO or PHP to develop their own practice guidelines, instead of using those already developed by expert panels. But, rather than specifying how many or which practice guidelines MCOs and PHPs must adopt, HCFA expects each plan to establish a process for identifying and reviewing guidelines that are relevant to the health conditions of the enrolled population and to implement a process, in conjunction with its providers, to adopt and implement the guidelines. HCFA points out that this requirement is consistent with NCQA standards. 66 Fed. Reg. at 6328-29.

Further, the proposed rule would have required practice guidelines to be based on Areasonable medical evidence or a consensus of health care professionals in the particular field.

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Proposed

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438.336(a)(1). HCFA amended the language to require that the practice guidelines be based, in part, on

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clinical evidence

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rather than on

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medical evidence.

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HCFA made this change to clarify that the rule does not restrict practice guidelines to those based on clinical trials only and that practice guidelines do not have to be adopted for every

condition. Also, because of the variation in the evidence base that supports medical interventions, HCFA believes that it must be flexible and accept the use of guidelines not only developed by clinical evidence, but also those developed by a consensus of health care providers in a particular field. 66 Fed. Reg. at 6329.

To better describe the type of evidence that should serve as basis for a practice guideline, HCFA also replaced *Areasonable* with *Avalid and reliable*. ' 438.236(b)(1). *Id.* at 6329-30.

HCFA also notes that the term

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clinical evidence

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is much broader than

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medical evidence,

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in that the latter refers to actions and treatments related to physician practices, while the former extends to health care researchers as well as other health care providers, such as dentists, pharmacists, and nurses.

Id.

. at 6330.

Commenters were concerned that the proposed rule would restrict treatments for people with special needs who did not have access to clinical trials and to people with conditions for which there were no clinical trials, such as mental health conditions. HCFA clearly states that Athe lack of practice guidelines for a particular condition does not provide a basis for an MCO or PHP to fail to treat conditions for which there is no guidance.

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66 Fed. Reg. at 6329. In response to concerns that practice guidelines would override judgments about medical necessity for individuals and concern about how MCOs and PHPs would apply EPSDT standards in face of these guidelines, HCFA stated that its intent is not to substitute practice guidelines for professional judgement in the care of individuals and that such practice guidelines are not mandates and should be applied consistent with individual needs. 66 Fed. Reg. at 6330. While MCOs and PHPs may have grounds for withholding services or refusing to pay for services that are inconsistent with practice guidelines that have been adopted, beneficiaries have two means to challenge such denials: (1) individual appeals of denials; and (2) a request for review by the State Medicaid agency to review the guideline to see that it meets the requirements of

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438.236 that guidelines are evidence-based and up-to-date. 66 Fed. Reg. at 6330.

HCFA declined to require adoption of specific practice guidelines, because of the growing number of such guidelines, the variation in the strength of the evidence base supporting these guidelines, and the need for ongoing review and updating of guidelines, we are reluctant to single out a subset of practice guidelines as superior to all others and preferentially require adherence to them in this regulation.

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66 Fed. Reg. at 6329. However, HCFA includes examples of guidelines that would satisfy the requirement in the regulation

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the Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection.

438.236(b). HCFA stresses that it believes that adherence to the HIV guidelines is essential to providing quality HIV care and strongly recommend that MCOs and PHPs adopt such guidelines as long as they continue to meet the criteria in the regulations. 66 Fed. Reg. at 6329. HCFA declined to include specific immunization practice guidelines, stating that current law requires State Medicaid agencies to provide all immunizations recommended by the Advisory Committee on Immunization Practices as part of the EPSDT program.

In response to the proposed ' 438.336(b) requiring that the MCO disseminate the practice guidelines to all providers, to all enrollees, as appropriate, and to individual enrollees when they request them, HCFA received varying comments. Some recommended that practice guidelines be made available more broadly, including to enrollee representatives, advocates and the general public. Others thought the dissemination language too broad, creating a burden on MCOs and raised proprietary concerns. Yet, others wanted clarification of what

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as appropriate

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entailed. In response, HCFA clarified that its intent was dissemination of the practice guidelines to all providers who are likely to deliver the type of care that is subject to the guidelines. HCFA also believes that enrollees with particular health conditions may reasonably want to know whether a health plan has adopted any particular guidelines relevant to their treatment and would want a copy of any adopted guidelines. To make this intent more clear, HCFA adopted the language,

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Each MCO and PHP disseminates the guidelines to all affected providers, and upon request, to enrollees and potential enrollees.

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438.236(c); 66 Fed. Reg. at 6331.

HCFA rejected the recommendation that States monitor and MCOs report on compliance with

practice guidelines due to excessive costs and administrative burdens. HCFA, instead, emphasized dissemination of the guidelines as required under ' 438.236(c); 66 Fed. Reg. at 6330. HCFA also believes that compliance with practice guidelines can be monitored through the States = quality improvement strategy. 66 Fed. Reg. at 6330. Similarly, HCFA refused to specify that MCOs need to require their providers to adhere to practice guidelines.

Id

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Without discussion, HCFA amended the language on the timing for reviewing and updating practice guidelines from Aperiodically@ to Aperiodically as appropriate.@ Compare proposed ' 438.336(a)(4)

with

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438.236(a)(4).

' 438.240 B Quality Assessment and Performance Improvement Program

Proposed ' 438.240 required each MCO to have an ongoing quality assessment and performance improvement program, and specified the basic elements of such a program. Additional provisions have been added and clarifications made to this section.

In the preamble discussion to this section, the extent of State flexibility is emphasized. For example, in response to a suggestion that the rules should allow phase-in of full compliance and ongoing improvement over time, HCFA stated that States have the flexibility to set measures, establish minimum performance levels, and conduct performance improvement projects. 66 Fed. Reg. at 6331. States also can set minimum performance levels that can be realistically achieved by participating health plans and not be penalized with denial of FFP should the State set those standards to comply with the regulations and an individual health plan not meet those standards in a single instance. *Id.* States also can choose how many performance measurement projects to require from their MCOs and PHPs; impose standards in addition to those listed in the regulations; impose a greater number or diversity of performance improvement projects specific to an MCO or PHP or on a statewide basis; and consider other quality improvement projects health plans already are conducting. 66 Fed. Reg. at 6331-6332.

States also can include in their performance measures, process and outcome measures and A quality of life indicators.

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Id

. at 6333. States can choose, but are not required, to audit medical records as part of the quality monitoring and performance improvement program.

Id

. While states can choose HEDIS as the standardized tool for quality improvement measures, HCFA notes that HEDIS has limitations and may not service the complete needs of States to fully address the Medicaid population.

Id

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While States are given enormous flexibility and authority, there are limitations. For example, State authority does not diminish the responsibility of States to meet performance levels established by law, such as conducting EPSDT screening and providing EPSDT services. 66 Fed. Reg. at 6332. States cannot postpone the Quality Assessment and Performance Improvement provisions to give MCOs and PHPs the time to develop programs and systems, because health plans now have the responsibility to monitor care, and, as such, must have programs and data that can be used to measure performance. *Id*. In setting minimum performance levels, States must consider historical plan and FFS Medicaid performance data and trends, so as to establish minimum performance levels that are achievable, meaningful and equitable. ' 438.240(c)(2)(B);

66 Fed. Reg. at 6332. While States have the discretion in setting standards, the standards must be measurable and demonstrate numeric improvement (e.g. percentage in reduction of deficient care). 66 Fed. Reg. at 6332-33.

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Cultural competence

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is added as a required non-clinical area for MCO and PHP performance improvement projects.

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438.240(d)(5)(iii); 66 Fed. Reg. at 6334. As there is with Medicare, HCFA also explained that there is no authority in the statute to use successful NCQA reviews in lieu of required yearly measurement of performance under 42 U.S.C.

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1396u-2(c)(1). 66 Fed. Reg. at 6333. Finally, while not all areas of quality improvement have to be addressed every year, States must require each MCO and PHP to initiate one or more performance improvement projects per year.

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438.249(d)(3); 66 Fed. Reg. at 6333.

In ' 438.240(c)(2)(ii)(A), HCFA states that it may specify standardized quality measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs. In ' 438.240(b)(4), HCFA requires that MCOs and PHPs have mechanisms in effect to assess the quality and appropriateness of care furnished to enrollees with special health care needs. Section 438.240(a)(3) states that HCFA may specify standardized quality measures, and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs. In addition, performance improvement projects in clinical and non-clinical areas must address the entire Medicaid enrolled population in an MCO or PHP to whom the measure is relevant. Proposed 438.340(d)(2);

438.240(d)(2). HCFA added and/or maintained these provisions to address the concerns about quality of care for persons with special needs. 66 Fed. Reg. at 6331-32, 6333.

In response to a comment that quantifiable quality improvement could be difficult for MCOs and PHPs to achieve due to their lack of control over all of the factors impacting such improvement, HCFA agreed that it could be difficult but that health plans nevertheless should be held accountable for quality improvement because many factors are within their control. 66 Fed. Reg. at 6332.

With no comment, HCFA amended subparagraph (c)(1) to clarify that each MCO and PHP must measure its performance annually. *Compare* proposed ' 438.340(c)(1) *with* final ' 438.240(c)(1).

HCFA also stated that it has changed the upper payment limits to MCOs and PHPs with a different mechanism to contain managed care costs. In this way, the additional costs of complying with quality improvement can be considered in setting capitation rates. 66 Fed. Reg. at 6332.

Requirements to publish performance measurement tools and assessment results and external validation of MCO and PHP-reported quality measures are to be addressed in a separate rule. / *d* . at 6333-34.

' 438. 242 B Health Information Systems

In accordance with 42 U.S.C. ' 1396u-2(c)(1)(iii), HCFA proposed ' 438.342 that would require states to ensure that each MCO and PHP maintain a health information system that collects, analyzes, integrates, and reports data that achieves the purposes of the statute.

HCFA deleted the requirement that MCO and PHP health information systems should provide information on MCO and PHP solvency on the basis that it was not appropriate to include this data with enrollee-specific data. *Compare* proposed ' 438.342(a) *with* ' 438.242.(a); 66 Fed. Reg. at 6344-45. HCFA also eliminated the requirement that MCOs make all collected data routinely available to HCFA as well as to the State to reduce the burden on health plans. HCFA can obtain the data from the States and, upon request, from the health plans. 66 Fed. Reg. at 6335.

Without comment in this section, HCFA also clarified that information on Medicaid enrollee disenrollments pertains to disenrollments for other than loss of Medicaid eligibility. *Compare* proposed

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' 438.342(a)
with
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' 438.242.(a).

In response to comments requesting that HCFA require data collection on race, ethnicity, sex, age, disability, and primary language, HCFA noted that, with the exception of age and sex, these have been addressed in the final rule (e.g., ' 438.208 regarding disability; ' 438.10(b) regarding language spoken;

' 438.204(b)(1)(iii) regarding race and ethnicity). With respect to age and sex, however, HCFA believes that it does not need to expressly require data collection, because these are such fundamental pieces of demographic data that are needed to comply with the information requirements of this provision (and thus already are being routinely collected). 66 Fed. Reg. at 6334.

HCFA also pointed out that increased matching funds at a rate of 90 percent are available to states for system development design and implementation and a match of 50 percent is available for maintenance of existing systems. 66 Fed. Reg. at 6334.

HCFA declined to set forth national standards for collection on EPSDT encounter data, stating that while HCFA has a desire for consistency of information, it also must balance necessary State flexibility to implement their Medicaid programs. However, HCFA is working on several initiatives to standardize data collection on a national level. 66 Fed. Reg. at 6335.

^[1] States are required under 42 U.S.C. ' 1396u-2(c)(2) to conduct an annual, independent, external review of health plans. The BBA repealed this requirement that was previously at 42 U.S.C. ' 1396a(a)(30)(C) and implemented ' 1306u-2(c)(2) instead. The independent, external review requirements will be promulgated under separate rulemaking. 66 Fed. Reg. at 6334. Federal regulations at 42 C.F.R.

434.53 require state agencies to conduct periodic medical audits to insure that each contractor furnishes quality and accessible health care to enrolled recipients. This provision was removed by the final BBA regulations with comment. 66 Fed. Reg. at 6403.

^[2] The sub-heading, AProvision of Services,@ in proposed ' 438.306(e) was changed to AFurnishing of Services @ in final ' 438.206(e).

^[3] In response to comments suggesting that HCFA define the term Acomplex and serious medical conditions, @ HCFA deleted the term, and instead used in the final rule A enrolees with special needs, @ noting that this is the term used by Congress at ' 4705(c)(2) of the BBA. HCFA states that it has conceptualized this term to include: 1) children with special health care needs; 2) children in foster care; 3) individuals with serious and persistent mental illness/substance abuse; 4) homeless individuals; 5) older adults (65 years-old and older) with disabilities; and 5) adults under 65 who are disabled or who have a chronic condition, whether physical or mental. However, this is not an operational definition of persons

with special health care needs. 66 Fed. Reg. at 6211.

^[4] The heading of this section was changed from Aconfidentiality@ to Aconfidentiality and accuracy of enrollee records.

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The section also was reorganized to clarify the requirements that apply to MCOs and PHPs