

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 430, 431,434, 435, 438, 440, and 447

[CMS-2104-F]

RIN 0938-AK96

Medicaid Program; Medicaid Managed Care: New Provisions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Medicaid regulations to implement provisions of the Balanced Budget Act of 1997 (BBA) that allow the States greater flexibility by permitting them to amend their State plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without obtaining waivers if beneficiary choice is provided; establish new beneficiary protections in areas such as quality assurance, grievance rights, and coverage of emergency services; and eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs, such as, the enrollment composition requirement, the right to disenroll without cause at any time, and the prohibition against enrollee cost-sharing.

EFFECTIVE DATE: These regulations are effective on [OFR-- please insert 60 days after the date of publication in the **Federal Register**]. States will have until [OFR please insert 12 months after effective date of final rule] to bring all aspects of their State managed care program (that is, contracts, waivers, State plan amendments and State operations) into compliance with the final rule provisions.

FOR FURTHER INFORMATION CONTACT:

Subparts A and B -- Bruce Johnson	(410) 786-0615
Subpart C -- Kristin Fan	(410) 786-4581
Subpart D -- Deborah Larwood	(410) 786-9500
Subpart F -- Tim Roe	(410) 786-2006
Subpart H -- Donna Schmidt	(410) 786-5532
Subpart I -- Tim Roe	(410) 786-2006
Subpart J -- Bruce Johnson	(410) 786-0615

SUPPLEMENTARY INFORMATION:

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO access, a service of the U.S. Government Printing Office.

The Website address is <http://www.access.gpo.gov/nara/index.html>.

I. Background

A. General

In 1965, amendments to the Social Security Act (the Act) established the Medicaid program as a joint Federal and State program for providing financial assistance to individuals with low incomes to enable them to receive medical care. Under the Medicaid program, each State establishes its own eligibility standards, benefits packages, payment rates and program administration in accordance with certain Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the State's Medicaid "State plan" that we must approve. In addition to approving State plans and monitoring States for compliance with Federal Medicaid laws, the Federal role also includes providing matching funds to State agencies to pay for a portion of the costs of providing health care to Medicaid beneficiaries. Medicaid beneficiaries typically include low-income children and their families, pregnant women, individuals age 65 and older, and individuals with disabilities. (Throughout this preamble, we use the term "beneficiaries" to mean "individuals eligible for and receiving Medicaid benefits." The term "recipients" in the regulations text has the same meaning as the term "beneficiary.")

When the Medicaid program was created, coverage typically was provided through reimbursements by the State agency to health care providers who submitted claims for payment after they provided health care services to Medicaid beneficiaries. This reimbursement arrangement is referred to as "fee-for-service"

(FFS) payment. Before 1982, 99 percent of Medicaid beneficiaries received Medicaid coverage through fee-for-service arrangements. Since 1982, State agencies increasingly have provided Medicaid coverage through contracts with managed care organizations (MCOs), such as health maintenance organizations (HMOs). Through these contracts an MCO is paid a fixed, prospective, monthly payment for each beneficiary enrolled with the entity for health coverage. This payment approach is referred to as “capitation.” Beneficiaries enrolled in capitated MCOs are required to receive health care services provided under the MCO’s contract, through the MCO that receives the capitation payment. The Omnibus Budget Reconciliation Act (OBRA) of 1981 (Pub. L. 97-35 enacted on August 13, 1981) allowed State agencies to mandate that Medicaid beneficiaries enroll in MCOs, which increased the use of MCOs. In most States, mandatory enrollment takes place for at least certain categories of beneficiaries. To achieve this mandatory enrollment, before the enactment of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105-33, enacted on August 5, 1997), States were required to obtain a waiver of a Medicaid statutory requirement for beneficiary "freedom of choice" of providers. (State programs that offered beneficiaries voluntary enrollment in MCOs do not require these waivers.) As a result, in 1997, just before the passage of the BBA, almost 8.5 million Medicaid beneficiaries, or 43 percent of all Medicaid beneficiaries, were enrolled in MCOs for a comprehensive array of Medicaid services. Some of these beneficiaries and additional Medicaid beneficiaries were enrolled in other organizations that received capitated payment for a limited array of services, such as behavioral health or dental

services. These organizations that receive capitation payment for a limited array of services are referred to as “prepaid health plans (PHPs).”

While the Act was further amended in the 1980s and in 1990 to address certain aspects of Medicaid managed care, the BBA represents the first comprehensive revision to Federal statutes governing Medicaid managed care in over a decade. In general, Chapter One (subtitle H) of the BBA significantly renovated the Medicaid managed care program by modifying Federal statute to: (1) allow States to mandate the enrollment of certain Medicaid beneficiaries into MCOs without having to first seek a waiver of Federal statutory requirements; (2) eliminate requirements on the composition of enrollment in MCOs that had not been proven to be effective; (3) apply consumer protections that were receiving widespread acceptance in the commercial and Medicare marketplaces to Medicaid beneficiaries; for example, consumer information standards and standards for access to services; and (4) apply the advances and developments in health care quality improvement that are in widespread use in the private sector to Medicaid managed care programs. Specifically, sections 4701 through 4710 of the BBA provisions: (1) reduce requirements for State agencies to obtain waivers to implement certain managed care programs; (2) eliminate enrollment composition requirements for managed care contracts; (3) increase beneficiary protections for enrollees in Medicaid managed care entities; (4) improve quality assurance; (5) establish solvency standards; (6) protect against fraud and abuse; (7) permit a period of guaranteed eligibility for

Medicaid beneficiaries; and (8) improve certain administrative features of State managed care programs.

We have already implemented provisions of the BBA that did not require regulations. CMS provided guidance on these provisions through the issuance of State Medicaid Director letters, which are listed below. These letters can be found on the CMS website at www.hcfa.gov/medicaid/letters/.

**STATE MEDICAID DIRECTOR LETTERS
ON MANAGED CARE PROVISIONS OF THE BBA**

<u>Section of the Act Issued</u>	<u>Subject</u>	<u>Date</u>
1932(a)(1)	State Plan Option for Managed Care	December 17, 1997
1932(b)(1)	Specification of Benefits	December 17, 1997
1932(d)(2)	Marketing Restrictions	December 30, 1997
1932(b)(6), 1128B(d)(1), 1124(a)(2)(A), 1932(d)(3), 1903(i), 1916(a)(2)(D), 1916(b)(2)(D), and 1903(m)(1)(C)	Miscellaneous Managed Care Provisions	December 30, 1997
1932(a)(1)(B) 1932(a)(3), and 1903(m)(2)(A)	Definition of a managed care entity, Choice, Repeal of 75/25, and Approval Threshold	January 14, 1998
1932(c)(2) and 1903(a)(3)(C)	External Quality Review	January 20, 1998
1932(a)(4)	Enrollment, Termination, and Default Assignment	January 21, 1998
1905(t) and	PCCM Services Without Waiver	January 21, 1998

1905(a)(25)

1932(e)	Sanctions for Noncompliance	February 20, 1998
---------	-----------------------------	-------------------

1932(a)(5)	Provision of Information &	February 20, 1998
------------	----------------------------	-------------------

BBA Section 4710(a)	Effective Dates	
---------------------	-----------------	--

1932(b)(2)	Emergency Services	February 20, 1998
------------	--------------------	-------------------

1932(b)(4)	Grievance Procedures	February 20, 1998
------------	----------------------	-------------------

1932(d)(1)	Debarred Individuals	February 20, 1998
------------	----------------------	-------------------

1932((b)(3), 1932(b)(7), and 1932(b)(5)	Enrollee-Provider Communications, Antidiscrimination of Providers, and Adequate Capacity	February 20, 1998
---	--	-------------------

1932(d)(2)	Effective Date of Marketing Restrictions	February 20, 1998
------------	---	-------------------

1902(e)(2)	Guaranteed Eligibility	March 23, 1998
------------	------------------------	----------------

BBA Section 4710(c)	Application to Waivers	March 25, 1998
------------------------	------------------------	----------------

1932(b)(2)	Prudent Layperson Standard	May 6, 1998
------------	----------------------------	-------------

1932(b)(2)	Post-Stabilization services	August 5, 1998
------------	-----------------------------	----------------

1932(b)	Emergency Services	April 18, 2000
---------	--------------------	----------------

B. Statutory Basis

Section 4701 of the BBA enacted section 1932 of the Act, changes terminology in title XIX of the Act (most significantly, the BBA uses the term “managed care organization” to refer to entities previously labeled “health maintenance organizations”, and amends section 1903(m) to require that MCOs and

MCO contracts comply with applicable requirements in newly added section 1932 of the Act. Among other things, section 1932 of the Act permits States to require most groups of Medicaid beneficiaries to enroll in managed care arrangements without waiver authority granted under section 1915(b) or 1115(a) of the Act. Under the statute before the BBA, a State agency was required to obtain Federal authority to waive beneficiary free choice of providers in order to restrict their coverage to managed care arrangements. Section 1932 also defines the term "managed care entity" (MCE) to include MCOs and primary care case managers (PCCMs); establishes new requirements for managed care enrollment and choice of coverage; and requires MCEs and State agencies to provide specified information to enrollees and potential enrollees.

Section 4702 of the BBA amended section 1905 of the Act to provide for States to contract with primary care case managers without waiver authority. Instead, primary care case management services may be made available under a State's Medicaid plan as an optional service.

Section 4703 of the BBA eliminated a former statutory requirement that no more than 75 percent of the enrollees in an MCO be Medicaid or Medicare beneficiaries.

Section 4704 of the BBA created section 1932(b) of the Act to add increased protections for those enrolled in managed care arrangements. These protections include, the application of a "prudent layperson's" standard to determine whether emergency room use by a beneficiary was appropriate; criteria for showing adequate

capacity and services; grievance procedures; and protections for enrollees against liability for payment of an organization's or provider's debts in the case of insolvency.

Section 4705 of the BBA created section 1932(c) of the Act, which requires States to develop and implement quality assessment and improvement strategies for their managed care arrangements and to provide for external, independent review of managed care activities.

Section 4706 of the BBA provided that, with limited exceptions, an MCO must meet the same solvency standards set by States for private HMOs, or otherwise be licensed or certified by the State as a risk-bearing entity.

Section 4707 of the BBA enacted section 1932(d) of the Act to add protections against fraud and abuse, such as restrictions on marketing and sanctions for noncompliance.

Section 4708 of the BBA added a number of provisions to the Act to improve the administration of managed care arrangements. These include, provisions raising the threshold value of managed care contracts that require the Secretary's prior approval, and permitting the same copayments in MCOs as apply to fee-for-service arrangements.

Section 4709 of the BBA allows States the option to provide 6 months of guaranteed eligibility for all individuals enrolled in an MCE.

Section 4710 of the BBA specifies the effective dates for all the provisions identified in sections 4701 through 4709 of the BBA, and specifies that these provisions do not

apply to the extent they are inconsistent with the terms and conditions of waivers under section 1915(b) or section 1115 of the Act.

C. Federal Register Publications On September 29, 1998, we published in the **Federal Register** (63 FR 52022) a proposed rule to implement the above provisions of the BBA. In that 1998 proposed rule, we also proposed to strengthen regulatory requirements of PHPs by incorporating regulatory requirements that would otherwise apply only to MCOs. We received over 300 comments on the 1998 proposed rule. The comments were extensive and generally addressed all sections of that proposed rule. On January 19, 2001, we published in the **Federal Register** (66 FR 6228) a final rule with comment period that summarized, and responded to the public comments we received on the proposed rule. It also contained additional provisions not included in the 1998 proposed rule. Among these were revisions eliminating the existing “upper payment limit” (UPL) on risk capitation payments in §447.361, and replacing this limit with provisions in §438.6(c) setting forth requirements designed to ensure that rates were actuarially sound. We invited comments only on these last two changes.

In a **Federal Register** notice (66 FR 11546) published on February 26, 2001, we announced a 60-day delay in the effective date of the January 19, 2001 final rule with comment period. This 60-day delay postponed the effective date of the rule until June 18, 2001. This delay in effective date was necessary to give Department officials the opportunity for further review and consideration of the new regulations. During that review, we heard from key stakeholders in the Medicaid managed care

program, including States, advocates for beneficiaries, and provider organizations. These parties expressed strong (sometimes opposing) views about the regulation. In particular, concerns were expressed about the revisions based on public comments we received on the proposed rule. Other commenters raised concerns about how we chose to implement those provisions in the final rule without further opportunity for public comment.

As a result of these comments, on June 18, 2001, we published a final rule in the **Federal Register** that further delayed the effective date of the January 19, 2001 final rule with comment period an additional 60 days, from June 18, 2001 until August 17, 2001, (66 FR 32776) for further review and consideration on the most appropriate way to address the concerns expressed by key stakeholders. In response to these concerns, on August 20, 2001 we published a new proposed rule in the **Federal Register**. In addition, in order to give us the time to consider the public comments and take final action on the new proposed rule, we also published in the August 17, 2001 **Federal Register** an interim final rule with comment period that further delayed until August 16, 2002, the effective date of the January 2001 final rule with comment period.

The new proposed rule was published to address the concerns that were expressed to the Department during our review. After careful consideration, we decided the best approach was to make some modifications to the January 19, 2001 final rule and republish it as a proposed rule. This would enable the public the opportunity to comment on all of the provisions and revisions.

In developing the proposed rule, we were guided by several considerations. First, we gave serious attention to all the concerns that were communicated to us. Second, we tried to discern when a difference of opinion represented different goals or different methods of achieving the same goals. Finally, we believed that all commenters expressed the same goal, namely: strong, viable, Medicaid managed care programs that deliver high quality health care to Medicaid beneficiaries. We note that we have published elsewhere in this **Federal Register** a final rule withdrawing the January 19, 2001 final rule with comment period.

We have drafted the provisions of this final rule in full recognition of the statutorily designed structure of the Medicaid program as a Federal-State partnership. States are assigned the responsibility of designing their State programs, and typically do so addressing local, as well as State needs. We have drafted this final rule to recognize the responsibilities of the States and the need to employ different approaches to achieving the same goal within their varying State marketplaces and health care delivery systems.

Finally, we appreciate that new advances and findings in health care, health care quality assessment and improvement, and health services research unfold on an almost daily basis. In many instances, States have been at the forefront of implementing these new developments and innovations. We have sought to standardize, through regulation, those practices that have been found to be necessary to the delivery of high quality health care. We simultaneously have sought to continue to allow States, in consultation with their State and local partners and

customers (beneficiaries), to determine the best approach to implementing their managed care program when there is an absence of clear evidence about the superiority of a given approach.

Overall, we recognize the great diversity and sometimes “special needs” of Medicaid beneficiaries. While the greatest numbers (54 percent) of Medicaid beneficiaries are children, 11 percent are age 65 or older. Medicaid also serves as a significant source of health care for individuals with disabilities and conditions that place them at risk of developing disabilities. In 1997, more than 6 million children and adults were eligible for Medicaid on the basis of a physical, mental, or cognitive disability. The Medicaid program insures more than half of all people with Acquired Immune Deficiency Syndrome (AIDS) in this country and up to 90 percent of children with AIDS. Medicaid also is a significant source of health care coverage for individuals with serious and persistent mental illness, and children in foster care. Our report to the Congress, “Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care” (November 6, 2000), summarized existing evidence on effective practices in caring for individuals with special health care needs.

The regulations in this final rule are mostly set forth as new provisions in part 438. All new managed care regulations created under the authority of the BBA, other sections of existing Medicaid regulations pertaining to managed care, and appropriate cross references will appear in this new part. By creating this new part,

we aim to help users of the regulations to better understand the overall regulatory framework for managed care.

D. Overview of Medicaid Managed Care

Medicaid managed care programs have been in existence almost since the inception of the Medicaid program in 1965. In New York State, Medicaid beneficiaries were enrolled in the Health Insurance Plan of Greater New York beginning in 1967. The State of Washington began contracting with Group Health of Puget Sound in 1970, and, by 1972, various regional operations of Kaiser-Permanente served Medicaid beneficiaries in three different States. Initially, there were no statutory or regulatory provisions specifically addressing the use of managed care by State agencies.

As a result of the increasing use of managed care in Medicaid, Medicare and the private sector, statutory provisions and regulations have since been adopted to specifically address Medicaid managed care. In 1976, the Health Maintenance Organization Act put forth the first specific Federal requirements for Medicaid contracts with HMOs or comparable organizations, by essentially requiring, with some exceptions, that contracts with entities to provide “comprehensive” specified services, be entered into only with Federally qualified HMOs. By 1981, little more than 1 percent of Medicaid beneficiaries were enrolled in managed care. Further legislative and regulatory changes made in 1981 and 1982 made possible more widespread use of managed care by State agencies but were also accompanied by increased requirements in some areas (For example, OBRA 1981 required that

Medicaid enrollees be allowed to voluntarily disenroll without cause from HMOs. This was subsequently amended to permit a 6-month lock-in for individuals enrolled in federally qualified HMOs.) Until the enactment of the BBA, modification of the statutes and regulations governing Medicaid managed care after OBRA 1981 and the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97-248, enacted on September 3, 1982) has occurred in a piecemeal manner. The BBA represents the first major revision of the statutes governing Medicaid managed care in over a decade.

The period from 1981 to the present has seen significant changes in Medicaid managed care programs. While only approximately 250,000 Medicaid beneficiaries were enrolled in managed care in 1981, by 1997 this number had increased to over 15 million. As of June 2000, approximately 56 percent of the entire Medicaid population received at least some services through an MCO, PHP, or a primary care case management arrangement. In the last decade, a number of studies and reports have documented that State agencies need both flexibility and assistance to implement new approaches and tools to effectively administer their contracts with MCOs. A 1997 General Accounting Office Report entitled, "Medicaid Managed Care - Challenge of Holding Plans Accountable Requires Greater State Effort." indicated the need for priority attention to beneficiary information and education, and access to care and quality monitoring.

As noted above, Medicaid managed care contracts were originally entered into by some State agencies without any specific statutory provision for these

arrangements. When the Congress acted to regulate managed care arrangements, it limited the applicability of these statutory requirements to contracts that were comprehensive in the services they covered.

Specifically, the statutory requirements enacted by the Congress in section 1903(m) of the Act have always applied to contracts for inpatient services plus any one of the other services specified in section 1903(m)(2)(A) of the Act, or for any three of the non-inpatient services specified in section 1903(m)(2)(A) of the Act. Managed care contracts that were less than comprehensive remained exempt from all statutory managed care requirements. In recognition of this fact, we have in the past exercised our authority under section 1902(a)(4) of the Act to specify “methods of administration” that were “necessary for proper and efficient administration” to impose regulatory requirements on entities that were exempt from the statutory requirements in section 1903(m), either because they provided less than comprehensive services or because they were specifically exempted by the Congress from complying with section 1903(m) requirements. These entities were called “prepaid health plans,” or “PHPs.”

The regulatory requirements we applied to PHPs were not as stringent in many areas as those under section 1903(m). For example, while PHPs were subject to an enrollment composition requirement like comprehensive HMO contractors, the PHP enrollment composition requirement could be waived by the State for “good cause.” PHPs also were not subject to the section 1903(m) requirement that beneficiaries have the right to disenroll without cause at any time, and beneficiaries

enrolled in PHPs thus could have their ability to disenroll restricted under section 1915(b) waiver authority, (where the right to disenroll required under section 1903(m) could not be waived).

In part, because of the less stringent requirements that applied to PHPs, there has been a substantial growth in PHP enrollment. Some of these PHPs are single service managed care plans (for example, behavioral health plans) and their enrollees are also enrolled in other managed care plans for their routine primary and acute care. Other PHPs, such as the Health Insurance Plan (HIP) of New York, provide a full range of services, but were exempted by the Congress from the requirements in section 1903(m) of the Act. As discussed more fully below, certain PHPs are required to meet most of the provisions that apply to MCOs.

Concurrent with the increasing size of, and need for, stronger Medicaid managed care programs, over the last decade we have been developing improved tools, techniques, and strategies that State agencies can use to strengthen their managed care programs. In 1991, we began the Quality Assurance Reform Initiative (QARI) to provide technical assistance tools and assistance to State agencies. In 1993, we produced a QARI guide entitled, "A Health Care Quality Improvement System for Medicaid Managed Care - A Guide for States," which contained four areas of guidance for States: (1) a framework for quality improvement systems for Medicaid managed care programs; (2) guidelines for internal quality assurance programs of Medicaid HMOs and PHPs; (3) guidelines for clinical and health services focus areas and use of quality indicators and clinical practice guidelines; and

(4) guidelines for the conduct of external quality reviews conducted under section 1902(a)(30)(C) of the Act. In 1995, we worked collaboratively with the National Committee for Quality Assurance (NCQA) and the American Public Human Services Association to produce a Medicaid version of the Health Plan Employer Data and Information Set (HEDIS). HEDIS is a standardized quality performance measurement system used by private sector purchasers of managed care services, which we modified for use by State agencies. We contracted with NCQA to develop “Health Care Quality Improvement Studies in Managed Care Settings: Design and Assessment -A Guide for State Medicaid Agencies”.

In 1996, we undertook the Quality Improvement System for Managed Care (QISMC) initiative to accomplish several goals: (1) to update the 1993 QARI guidelines; (2) to develop coordinated Medicare and Medicaid quality standards that would reduce duplicative or conflicting efforts; (3) to make the most efficient and effective use of recent developments in the art and science of quality measurement, while allowing sufficient flexibility to incorporate developments in this rapidly evolving discipline; and (4) to assist the Federal government and State agencies in becoming more effective "value-based" purchasers of health care for vulnerable populations. In developing QISMC, we worked with representatives from, and with tools developed by, health plans, State agencies, advocacy organizations, and experts in quality measurement and improvement such as the NCQA, the Foundation for Accountability (FACCT) and the Joint Commission on the Accreditation of Healthcare Organizations. With the assistance of the experts and their products, we

identified the approaches, tools, and techniques that we believed would most effectively measure and improve health care quality in managed care. The quality assurance provisions of this final rule espouse the same philosophy and goals for performance improvement as are reflected in QISMC, but have been modified based on recent developments in Medicaid, managed care, and quality assessment and improvement. For example, QISMC was written before our report to the Congress addressing individuals with special health care needs.

In 1997, the Agency for Health Care Policy and Research (AHCPR) (now, the Agency for Healthcare Research and Quality) produced a set of consumer survey instruments and measurement tools under the auspices of the Consumer Assessment of Health Plan Study (CAHPS). The CAHPS instruments include measures and tools specifically designed for use by State agencies. Also in 1997, the George Washington University Center for Health Policy Research published a compendium of provisions of State contracts with Medicaid managed care organizations. This nationwide study of Medicaid managed care contracts has provided valuable information that can be used by all State agencies in the design and management of their managed care contracts.

More recently, in 1999, we produced a technical assistance manual for State agencies entitled, "Writing and Designing Print Materials for Beneficiaries: A Guide for State Medicaid Agencies." This technical assistance tool for States was in direct response to the BBA statutory provisions calling for dissemination of information to Medicaid beneficiaries. A contract with FACCT produced a manual describing valid

and reliable tools that State agencies can use to identify children and adults with special health care needs. In addition, a contract with the Center for Health Program Development and Management at the University of Maryland Baltimore County will develop a guidance manual for States that will describe various approaches to using health status-based risk adjustment in making payments to MCOs.

These and other tools we have in planning stages can be applied to the efforts of State agencies to become even more effective in purchasing managed care services for Medicaid beneficiaries. This final rule provides an opportunity to clarify for MCOs, beneficiaries, and State agencies, how these advances in the management and oversight of health care can be applied to Medicaid managed care programs.

Through these regulations, we promote uniform national application of knowledge and best practices learned from these initiatives. While we promote uniform best practice, the Medicaid statute has always given State agencies latitude to design their Medicaid programs, as long as they meet certain minimum Federal standards. Current Federal requirements in the Medicaid managed care area are imposed either as conditions for Federal matching funds to support contracts with MCOs, as conditions for receiving a waiver of freedom of choice under section 1915(b) of the Act, or as conditions for falling within the section 1932 exception to the freedom of choice requirement in section 1902(a)(23) of the Act. In the first case, failure to comply with section 1932 requirements could result in a disallowance of Federal financial participation (FFP) in contract payments. In the latter two cases, if the State fails to meet conditions for the section 1932 exception to the freedom-of-

choice requirement in section 1902(a)(23), or has its section 1915(b) waiver nonrenewed or terminated for a failure to meet waiver conditions, the State agency would be out of compliance with the freedom of choice requirement in section 1902(a)(23), and the State agency would be subject to a compliance enforcement action under section 1904 of the Act.

Because the Medicaid program is a State-administered program subject to Federal guidance and rules, Medicaid regulations do not generally adopt the same approach to regulating managed care organizations as Federal Medicare regulations. Instead, Medicaid rules generally regulate State agencies and place requirements on their contracts with managed care organizations or managed care programs. This final rule adopts this direction in implementing the new requirements in the BBA.

Section 4710(c) of the BBA provided for a time-limited exemption from the requirements in sections 4701 through 4710 for approved waiver programs or demonstration projects under the authority of sections 1115 or 1915(b) of the Act. Specifically, the BBA in section 4710(c) provided that none of the provisions contained in sections 4701 through 4710 would affect the terms and conditions of any approved section 1915(b) waiver or demonstration project under section 1115, as the waiver or demonstration project was in effect on the date of the enactment of the BBA (that is, August 5, 1997.) We interpreted this “grandfather provision” to apply only for the period for which the waiver or demonstration project was approved as of August 5, 1997. Thus, at the expiration of any 2-year waiver period under section 1915(b), or at the end of the period for which a demonstration project was approved

under section 1115, the grandfather provision in section 4710(c) would no longer apply.

In general, during the period approved as of August 5, 1997, any provision of a State's approved section 1115 or section 1915(b) waiver program that was specifically addressed in the State's waiver proposal, statutory waivers, special terms and conditions, operational protocol, or other official State policy or procedures approved by us, was not affected by the BBA provisions, even if it differed from the BBA managed care requirements. As long as the BBA provisions were addressed in the State's approved waiver materials, no determination needed to be made as to whether the State's policy or procedures meet or exceeded the BBA requirements. If the BBA provisions were not addressed, the State was required to meet the BBA requirements, except as specified below for newly submitted or amended waivers.

As noted above, under our interpretation, the exemption from the BBA requirements applied to section 1915(b) waiver programs only until the date that the waiver authority approved or in effect as of August 5, 1997 expired, which in all cases occurred no later than 1999. As of the date of the two year section 1915(b) waiver period approved on August 5, 1997 expired, the State was required to comply with all BBA requirements that in effect.

In the case of section 1115 demonstrations, while the "grandfather" provision in section 4710(c) only applies until the end of the period for which the demonstration project was approved as of August 5, 1997, if the demonstration project has been extended under the provisions in section 1115(e) of the Act, existing

terms and conditions inconsistent with BBA requirements are extended for three years, nullifying the effect of the "expiration" of the grandfather provision in section 4710(c). Therefore, any exemptions from the BBA requirements to which these programs were entitled under the "grandfather provision" may continue during the period of the extended waiver authority.

The Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000 (Pub. L. 106-554) provided for additional extensions of section 1115 health care reform demonstrations, but did not include language extending the same terms and conditions through this period. Thus, we conclude that provisions of the BBA would apply to the demonstrations in these extension periods under BIPA as well as all other demonstrations in extensions under any authority other than section 1115(e)(2), unless the Secretary uses his discretionary authority to waive the requirements.

For newly submitted or amended section 1915(b) or section 1115 waivers, the Secretary retains the discretionary authority to waive the BBA managed care provisions. Generally, waivers are granted that allow States some flexibility in operating their Medicaid programs, while promoting the proper and efficient administration of a State's plan. In particular, for the BBA provisions related to increased beneficiary protections and quality assurance standards, we anticipate that the BBA provisions would apply unless a State can demonstrate that a waiver program beneficiary protection or quality standard would equal or exceed the BBA requirement.

II. Provisions of the Proposed Rule and Analysis of and Response to Public Comments

We received comments from 387 States, national and State organizations, health plans, advocacy groups and other individuals on the August 20, 2001 proposed rule. The comments were extensive and generally pertained to the new rate-setting provisions, the quality requirements and the grievance system requirements contained in the proposed rule. We carefully reviewed all of the comments and revisited the policies contained in the proposed rule that related to the comments. This final rule responds to these comments. In the following discussion, we present a summary of the proposed provisions and our responses to the public comments.

In the proposed rule, we set forth the new organizational format for part 438 as follows:

Subpart A--General Provisions

Subpart B--State Responsibilities

Subpart C--Enrollee Rights and Protections

Subpart D--Quality Assessment and Performance Improvement

Subpart E--[Reserved]

Subpart F--Grievance System

Subpart G [Reserved]

Subpart H--Certifications and Program Integrity

Subpart I--Sanctions

Subpart J--Conditions for Federal Financial Participation

A. General Provisions (Subpart A)

1. Basis and Scope (Proposed §438.1)

Section 438.1 of the proposed regulation set forth the basis and scope of part 438 including the fact that regulations in this part implement authority in sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act. Proposed §438.1 also briefly described these statutory provisions.

2. Definitions (Proposed §§400.203, 438.2, 430.5)

Sections 400.203, 438.2 and 430.5 of the proposed rule included definitions of terms that would apply for purposes of proposed part 438. In reviewing the definitions in this section of the proposed rule, we recognized that the current definition of health insuring organization (HIO) is confusing, and not useful to the reader. The current definition encompasses entities that also meet the definition of managed care organization (MCO), and are subject to MCO requirements. This is because the language in section 1903(m)(2)(A) contemplates that there would be HIOs that are subject to the requirements in that section, including the requirement that the HIO meet the definition of MCO. (The introductory clause to the requirements in section 1903(m)(2)(A) includes the parenthetical "including a health insuring organization.")

This language dates to a time when HIOs that arranged for care were exempt from the MCO requirements in section 1903(m)(2)(A). Specifically, the language was added in 1985 legislation (the Consolidated Omnibus Budget Reconciliation Act

of 1985 (COBRA)) that "grandfathered" this exemption for HIOs operating before January 1, 1986. The parenthetical language was designed to make clear that other "HIOs" would be subject to 1903(m)(2)(A) requirements. Because one of the requirements of section 1903(m)(2)(A) is meeting the definition of MCO, any entity in this latter category would be covered by references in the regulations to MCOs. Thus, the term HIO has no legal significance for these entities. The term HIO is only relevant insofar as an exemption from section 1903(m)(2)(A) uses this term to refer to the exempt entity.

In the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), the Congress again used the term HIO, in exempting certain county-operated entities in California from section 1903(m)(2)(A) requirements. After these amendments, the term HIO is only legally relevant for purposes of identifying this new group of exempt entities, and the entities grandfathered in COBRA. For this reason, and to avoid confusion, in this final rule, we are changing the definition of HIO to refer only to these section 1903(m)(2)(A)-exempt entities for which the term has continuing legal relevance. This change has no effect on any entities' rights or obligations.

Also among these definitions are new definitions of a "Prepaid Inpatient Health Plan" (PIHP) and a "Prepaid Ambulatory Health Plan" (PAHP). These new definitions divide the definition of "Prepaid Health Plan" (PHP) in the January 19, 2001 final rule into two subcategories of PHPs, to which different regulatory requirements would apply in this final rule. PIHPs are entities that provide some inpatient services, and would be subject to more requirements than PAHPs, which do

not provide inpatient services. We received the following comments on the proposed definitions in the proposed rule, including the new proposed definitions of PIHP and PAHP.

Comment: One commenter expressed concern that the proposed definition of “provider” included in §400.203 encompasses all entities and individuals engaged in, or arranging for, the delivery of a medical service in a managed care delivery system. The commenter believed that this broad definition creates a problem when applied in proposed §438.214(b), which requires the credentialing of providers who participate with an MCO or PIHP. The commenter contended that including all ancillary and non-licensed providers under this credentialing requirement goes far beyond current industry standards that apply only to licensed health professionals such as physicians, psychologists, podiatrists, and mid-level practitioners. The commenter suggested limiting the scope of the requirements in §438.214(b) to those health professionals that are engaged in the delivery of direct patient care and are licensed within their State.

Response: The definition of “provider” as published in our proposed rule, mirrors the definition of provider used in the Medicare+Choice regulations. However, to further clarify the definition in the proposed rule, and to be consistent with the definition of “physician” used in section 1861(r)(1) of the Act, we revised the definition of “provider” to be “any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.” We believe that the proposed definition is correct,

and the requirements that States have a process for credentialing and recredentialing all individuals involved in the delivery of health care services is an appropriate beneficiary protection. There is no requirement that the process be the same for each provider type within a network, only that there be a process in place. Further, this definition provides States the flexibility to determine what State requirements any provider must meet (for example, licensure and certification requirements) in order to provide services under managed care arrangement, and allows States, at their option, to include licensure or certification requirements imposed by tribal governments.

Comment: One commenter suggested that we add the definition of health care professional in §438.102 to this section.

Response: Proposed §438.102(a) contains the statutory definition of health care professional found in section 1932(b)(3)(C) of the Act, which specifically applies to the provisions governing enrollee-provider communications. However, in light of the fact that this term is also used for other purposes throughout part 438, we agree with the commenter that the definition of health care professional in proposed §438.102 should be moved to §438.2, and have done so.

Comment: A large number of commenters opposed the separation of PHPs into PIHPs and PAHPs. Some felt that we had not provided sufficient reasons for making this distinction, that the primary purpose of the change was to exempt a broad catch-all category of PAHPs from regulatory standards, and argued that defining the entity and the level of regulation based on the scope of the services

provided was not logical, and could deny beneficiaries needed protections. These commenters felt that this distinction could jeopardize the quality and consistency of health care, particularly for women, due to the PAHPs' exemption from anti-discrimination provisions, State quality strategies, adequate service and capacity requirements and grievance and appeal rights. The commenters further noted that the January 19, 2001 final rule would apply to all PHPs. Several commenters felt that the new definitions could lead to gaming by contractors and create an incentive for MCOs or PIHPs to carve out various services (for example, inpatient hospital services) in order to limit the degree to which they are regulated. One commenter suggested that the term PAHP be more clearly defined, or limited to a specific set of non-medical or non-health care services, in order to prevent such carve-outs.

Some commenters wanted to return to the original PHP definition and subject all PHPs to all MCO requirements, while others suggested keeping the current PHP definition but allowing for individual rules to be relaxed where they are inapplicable.

Other commenters supported making the distinction between types of PHPs and believed that basing this distinction on the scope of services is a useful way to distinguish between requirements that are relevant to each contracting arrangement, and to provide the flexibility needed to appropriately regulate each type of contractor.

Response: We believe that the distinction between types of PHPs established in the proposed rule is appropriate and we will maintain the separate definition of PIHP and PAHP in this final rule. There are clear differences in terms

of the degree of financial risk, contractual obligation, scope of services, and capitation rates paid to these different types of entities. The distinction between PIHPs and PAHPs based upon the scope of services in their contract is modeled after the requirement in section 1903(m)(2)(A) of the Act, which defines the scope of contracted services that requires an MCO. This scope of services is set forth in §438.2, which defines comprehensive risk contract as a risk contract that covers inpatient hospital services and any of the following services, or any three or more of the following services: (1) Outpatient hospital services; (2) Rural health clinic services; (3) FQHC services; (4) Other laboratory and X-ray services; (5) Nursing facility (NF) services; (6) Early and periodic screening diagnostic, and treatment (EPSDT) services; (7) Family planning services; (8) Physician services; or (9) Home health services.

PHPs were originally designated by regulation as entities that incurred risk for a lesser scope of services. Since that time, the PHP definition has been expanded to include a scope of services that would have required an MCO, except that their contracts covered only a portion of inpatient hospital services (for example, inpatient mental health services) rather than all inpatient hospital care. These entities incurred far greater risk, were obligated to provide a greater range of services, and have greater responsibility for the beneficiary care than the early PHPs, which were predominantly capitated primary care physicians and physician groups at risk for the cost of physician and one other outpatient Medicaid service.

Recognizing that the scope of contractual responsibility for these larger

PHPs, now designated PIHPs, was far more like the responsibilities in MCO contracts, we have imposed most MCO requirements on these entities. The PAHP designation allows us to impose requirements on this smaller group that are more appropriate to the scope of services they are obligated to provide. Not only do we believe it is unnecessary to subject prepaid dental plans, transportation providers, and capitated primary care case managers to the same standards as MCOs and PIHPs, it is not logical to impose the same administrative burdens on contractors who receive a fraction of the amount in capitation rates that MCOs and PIHPs are paid. Further, for these types of entities, access to care could be negatively impacted by the imposition of inappropriate levels of administrative burdens.

Further, we do not believe it likely that MCOs and PIHPs that contract with States will arbitrarily reduce the benefit package they provide in order to limit the degree to which they are regulated. First, much of the savings to be achieved from managed care come from reductions in the cost of inpatient care for beneficiaries, and a contractor would not likely choose to carve-out the source of most of their potential savings. Neither is it to the State's advantage to permit such carve-outs, since the State would then be obligated to assume all responsibilities for coordination of care required under Subpart D that would otherwise be the contractor's responsibility.

Finally, we believe that the distinction is clear between PIHPs and PAHPs and MCOs. If an entity has less-than a comprehensive risk contract, but has any responsibility for an enrollee's inpatient hospital or institutional care, it is a PIHP and

subject to all PIHP requirements. However, as discussed below, in §438.8 we have expanded the requirements that apply to PAHPs, as described in that section.

Comment: Several commenters felt that many PHPs that provide a comprehensive range of services; (for example, outpatient services, including primary care, mental health care, reproductive health care, and/or HIV services), but do not provide inpatient care should not be exempt from the managed care requirements in the proposed rule. One commenter asked whether an entity responsible only for behavioral health services (inpatient and outpatient) is considered a PIHP.

Response: In making the distinction between PIHPs and PAHPs, we have not changed current policy under which entities that contract for a subset of inpatient and outpatient care, as with behavioral health carve-outs, do not have comprehensive risk contracts subject to the statutory requirements that apply to MCOs. Thus, in answer to the commenters' question, such a behavioral health contractor is a PIHP (due to its provision of some inpatient services), not an MCO. Similarly, the definition of comprehensive risk contract in section 1903(m)(2)(A) of the Act has not changed, so that an entity that is at risk for inpatient hospital services generally, and any one of the other specified services, or three or more of the services identified in the definition of comprehensive risk contract, falls under the MCO requirements in section 1903(m)(2)(A).

Comment: Several commenters argued that ambulatory and community-based plans should not be exempt from essential protections, while others felt that

these programs did not need to be included as PIHPs.

Response: We are not expanding the PIHP definition to include these programs. If these programs are responsible for institutional care, they will be subject to PIHP requirements. Otherwise, we believe their scope of risk and operations for these programs are more like PAHPs.

Comment: One commenter believed that the use of the terms PIHP and PAHP would permit States to mandate enrollment in PIHPs and PAHPs of populations who were exempted from mandatory enrollment in MCOs and PCCMs under the authority in section 1932(a).

Response: The authority in section 1932(a)(1) of the Act and proposed §438.50 permitting States to mandate managed care enrollment through a State plan amendment does not extend to certain specified groups of beneficiaries who are exempted from having managed care enrollment mandated under that provision. In addition, the authority in section 1932(a)(1) is limited to mandating enrollment in MCOs and PCCMs, and does not give States authority to mandate enrollment in either PIHPs or PAHPs, unless the PAHP qualifies as both a PCCM and a PAHP. But, this would still not permit the mandatory enrollment of the exempted groups under section 1932(a). However, the exemption of certain populations from mandatory enrollment under section 1932(a)(1) applies only to enrollment under the new authority in that section, and did not preclude the mandatory enrollment of these groups of beneficiaries in MCOs, PCCMs, PIHPs, or PAHPs under existing authority in sections 1115 or 1915(b) of the Act.

Comment: One commenter believes that the definition of "primary care" should include services provided by a Master of Social Work, psychologist, psychiatrist, physician assistant, advanced registered nurse practitioner, or other health care professional.

Response: The definition of primary care in this section is taken from section 1905(t)(4) of the Act, which specifically identifies the services that the Congress intended to be included as primary care. We do not believe adding the services suggested by the commenter would be an appropriate extension of this section of the Act. We note, however, that States have the option of using physician assistants, certified nurse midwives, and nurse practitioners as primary care case managers, although the primary care services they provide would still be as defined in this section.

3. Contract Requirements (Proposed §438.6)

Proposed §438.6 set forth rules governing contracts with MCOs, PIHPs, PAHPs and PCCMs. Paragraph (a) of proposed §438.6 required the CMS Regional Office to review and approve all MCO, PIHP and PAHP contracts, including those that are not subject to the statutory prior approval requirement implemented in §438.806. Paragraph (b) set forth the entities with which a State may enter into a comprehensive risk contract. Paragraph (c) proposed new rules governing payments under risk contracts, to replace the upper payment limit in §447.361. Paragraph (d) contained requirements regarding enrollment; that enrollments be accepted in the order of application up to capacity limits, that enrollment be voluntary unless

specified exceptions apply, and that beneficiaries not be discriminated against based on health status. Paragraph (e) provided that MCOs, PIHPs, and PAHPs can cover services for enrollees in addition to those covered under the State plan. Paragraph (f) required that contracts must meet the requirements in §438.6. Paragraph (g) required that risk contracts provide that the State and HHS have access to financial records of contractors and subcontractors. Paragraph (h) required compliance with physician incentive plan requirements in §§422.208 and 422.210. Paragraph (i) required compliance with advance directive requirements. Paragraph (j) provided that with certain exceptions, HIOs are subject to MCO requirements. Paragraph (k) proposed new rules from section 1905(t)(3) of the Act that apply to contracts with primary care case managers. Paragraph (l) and (m) set forth existing requirements for subcontracts and enrollees' right to choice of health professional to the extent possible and appropriate, respectively. Because of the volume of comments we received on this section, we have grouped our comments and responses according to the paragraph designation. We note that we did not receive comments on paragraphs (a), (b), (d), (h) and (j) of this section and are therefore implementing those provisions as proposed.

? **Payment Under Risk Contracts (Proposed §438.6(c))**

General Comments

This section proposed new rules to replace the upper payment limit (UPL) for risk contracts in §447.361, which is being repealed as part of this final rule. The new rules require actuarial certification of capitation rates; specify data elements that

must be included in the methodology used to set capitation rates; require States to consider the costs for individuals with special health care needs or catastrophic claims in developing rates; require States to provide explanations of risk sharing or incentive methodologies; and impose special rules, including a limitation on the amount that can be paid in FFP under some of these arrangements.

Comment: Nearly all commenters expressed strong support for replacing the UPL with an actuarial process and methodology requirement.

Response: We appreciate the commenters' support. We have been working for several years to move away from the UPL requirement for risk-based managed care contracts and appreciates the input it has received from a number of sources including States, managed care entities, actuaries, and various organizations in this process. There was a broad consensus among these parties to eliminate the UPL requirement.

Comment: Commenters wanted us to allocate additional resources to ensure that the agency has the necessary expertise to review rates and to provide technical assistance to States in order to implement the new rate setting process.

Response: We have been providing training and tools to review payment rates under these rules to our regional office personnel who are responsible for the review all of the MCO, PIHP, and PAHP risk contracts using this new methodology. The rate review checklists to be used by our regional offices are available from CMS regional offices. Section 1903(k) of the Act specifically authorizes us to provide this assistance to States at no cost, although most States have currently elected to contract

with their own actuaries. If States request this assistance as these new requirements are implemented, we will provide it.

Comment: One commenter asked what appeals process is available for rate disputes. Another commenter recommended that we establish a mechanism to mediate disputes between MCOs and States over rates similar to the mediation process currently used in one State, involving: (1) meetings between State and MCO actuaries where there is a dispute, during which the parties identify areas of continued disagreement; and (2) selection of a mutually acceptable independent actuary to mediate the dispute and make his/her (non-binding) findings available to the State and MCO.

Response: Some States have formal processes for appeals or dispute resolution on payment rates, while in others there may be a more informal process for this purpose. While we support these mechanisms to emphasize the partnership between States and MCOs in Medicaid managed care, and believe they may help to sustain the viability of these programs, we do not believe it would be appropriate for the Federal government to impose specific requirements on States. Rather, we believe that a State should have the flexibility to provide for the processes that works best for that State.

Comment: A number of commenters believed that State rate setting processes should be more open, and that States should be required to disclose core data assumptions regarding the State's rate setting methodology, utilization data for each rate category, and trend factors used. Several other commenters suggested that

we require States (other than those using a competitive bidding process) to disclose sufficient information to permit MCOs to replicate the calculation of proposed rates, including the unit cost and utilization assumptions used and assumptions used in calculating administrative cost and retention factors. These commenters believe that this sharing of information will permit informed discussions between States and MCOs in the process and increase the continued viability of Medicaid managed care programs.

Response: We agree that sharing information in a negotiated rate setting process to the extent possible is a good way to enhance the partnership between States and MCOs and to maintain the viability of a State's Medicaid managed care program. However, we recognize that this will not always be possible and may not be a preferred contracting approach in some markets, even where competitive bidding is not the rate setting mechanism used by a State. Consequently, we are not willing to impose a Federal requirement that certain information be shared, and continue to believe that MCOs, PIHPs, and PAHPs contracting with States on a risk basis must make their own independent judgments of proposed rates based on their own costs of doing business and their understanding of the population to be covered.

Comment: One commenter asked how States would be required under the new rules to make payment adjustments to account for changes in trends or new administrative requirements that occur between legislative sessions or contract renewals.

Response: Contracts may be of varying lengths, but any changes to the terms

of a contract during that period require a contract amendment that must be reviewed and approved by us. FFP is available for such amended contracts only after both parties have agreed to the changes and CMS has approved the contract amendment. We will not require States to amend contracts due to changes in such things as trends in inflation rates, unless payment rates are changed as a result. However, we believe that changes in the services to be provided or the administrative requirements in a contract would warrant changes in payment rates to reflect the expected impact of the required change in services or administration.

Comment: A commenter asked what would occur if a State refuses to pay rates that have been approved by CMS as actuarially sound. The commenter wanted to know how we would enforce these rates.

Response: We only review the rates that are submitted by States as part of the contract review process. We believe it would be unlikely that States would submit capitation rates for contract approval, and then not pay the approved rates. In the event that this were to occur, and be documented, the State would be subject to a disallowance of FFP for failing to comply with the requirement in section 1903(m)(2)(A)(iii) that rates be actuarially sound.

Comment: One commenter was concerned that eliminating the UPL and requiring actuarially sound capitation rates may increase the burden if States need to continue to calculate a UPL to determine cost effectiveness. Another commenter noted that we had indicated in the proposed rule that we would issue a revised methodology for determining the cost effectiveness of section 1915(b) waivers, and

wanted to know (1) when waiver applications would be modified to contain the new methodology and (2) how States are to document cost effectiveness in the interim.

Response: We do not wish to impose additional burden on States in moving from the UPL test to a rule that requires an actuarially sound methodology as set forth in this final rule. As the commenter noted, we are issuing new cost effectiveness requirements for section 1915(b) waiver applications for both new and existing waivers, which will more closely correspond to the principles in the new rate setting guidelines. We expect to issue new guidelines for cost effectiveness before the effective date of this regulation, and will attempt in these guidelines to reduce the burden on States in documenting the cost effectiveness of these waiver programs. Recognizing the difficulty in changing long-standing methodologies in both setting rates and documenting cost effectiveness, we will permit States to use either the current methodology with its FFS comparison, or the rate setting process in this regulation in the period between the effective date of these rules and the final implementation date.

Comment: One commenter asked if we have any guidelines or regulations on the length of time FFS data must be retained, since these data still have some use in setting capitation rates.

Response: We agree that FFS data are one of the possible sources for establishing base year costs and utilization under this rule. However, one of the reasons for moving to the new rate setting rules, and away from the UPL requirement, is that FFS data loses its validity for this purpose as it becomes older.

We are not establishing any rule as to the age of data used for rate setting purposes, since we would rely on an actuarial certification that the data used had sufficient validity for this purpose. For the retention of FFS data in general, §433.32(b) and (c) require States to retain records, such as FFS data, for 3 years from the date of submission of a final expenditure report (or longer if audit findings have not been resolved). We believe that these data have value for rate setting purposes beyond the time period they are required to be retained under that regulation.

Comment: One commenter suggested that requirements for actuarial soundness extend to payment rates between MCOs and subcontracting providers.

Response: Except in the case of payments to FQHCs that subcontract with MCOs, which are governed by section 1903(m)(2)(A)(ix), we do not regulate the payment rates between MCOs and subcontracting providers. While section 1903(m)(2)(A)(iii) requires that payments to MCOs be actuarially sound, other than in the case of FQHCs, the Congress has not established any standards for payments to subcontractors. We believe that this is because one of the efficiencies of managed care is premised on an MCO's ability to negotiate favorable payment rates with network providers. MCOs must pay sufficient rates to guarantee that their networks meet the access requirements in subpart C of this final rule. We believe that payment rates are adequate to the extent the MCO has documented the adequacy of its network.

Definition of Actuarially Sound Capitation Rates

Comment: Many commenters believed that CMS should go beyond simply

defining an actuarially sound process, and instead should establish prescriptive standards for actuarial soundness. Some commenters believed that the definition of "actuarially sound capitation rates" should include the concept that rates be sufficient to cover the reasonable costs of the MCO. Other commenters suggested that we adopt the definition of actuarial soundness adopted by the Health Committee of the Actuarial Standards Board in the context of the small group market, which requires that payments "are adequate to provide for all expected costs, including health benefits, health benefit settlement expenses, marketing and administrative expenses, and the cost of capital. Another commenter believed the definition of actuarially sound rate setting should be replaced with language similar to the following: rates are determined using generally accepted actuarial methods based on analyses of historical State contractual rates and an MCO's experience in providing health care for the eligible populations, and are paid based on legislative allocations for the Medicaid program. Several other commenters supported our proposed approach requiring that rates be developed using accepted actuarial principles and practices.

Response: As discussed in detail below, we considered various approaches in defining actuarial soundness, but decided that basing the definition on a methodology that uses accepted actuarial principles and practices, and that is certified by a member of the American Academy of Actuaries, is the best approach in that it gives States and actuaries maximum flexibility while still ensuring that rates be certified as actuarially sound.

Comment: A number of commenters wanted the actuarial soundness test at

§438.6(c)(1)(i) to be revised to require that payment rates be adequate to cover the actual cost of services to be provided, and wanted us to take a more active role in assuring the adequacy of rates, including; (1) reviewing key components and underlying assumptions of the rates, rather than accepting an actuary's certification; (2) ensuring proper adjustment and enforcement of the payment rules; (3) disapproving rates determined to be inadequate; (4) requiring disclosure of rate calculation inputs; and (5) resolving rate calculation disputes between MCOs and States. In contrast, several other commenters believed that we had gone too far in establishing a standard for rate adequacy that would be difficult to administer and justify.

Response: While, as indicated above, there was a consensus among commenters on the need to replace the UPL requirement, there were a wide variety of opinions among commenters on requirements to replace it. In the proposed rule, we sought to strike a balance between merely accepting State assurances on capitation rates in risk contracts on one hand, and requiring that the amounts of the capitation rates paid in each contract meet specific requirements for reasonableness and adequacy on the other. Under the former concept, we did not believe that we would meet our statutory responsibility to ensure that rates are actuarially sound as required under section 1903(m)(2)(A)(iii). Under the latter format, we would be establishing standards for reasonableness and adequacy of rates, which: (1) would require that a determination be made on every rate cell in each risk contract submitted to us for review; (2) would require that we obtain sufficient actuarial

expertise to review every risk contract in Medicaid managed care; and (3) would establish a new “reasonable and adequate” payment standard for Medicaid managed care when, in the BBA, the Congress amended title XIX to eliminate a similar requirement for Medicaid payments to institutional providers.

As a result of these considerations, we have established a requirement that payment rates in risk contracts be actuarially sound, that is, that they have been developed in accordance with generally accepted actuarial principles and practices, are appropriate for the populations and services under the contract, and have been certified by an actuary as meeting the requirements in this rule and the standards of the Actuarial Standards Board. This rule then sets forth the basic requirements that States must apply in setting capitation rates, and the documentation that States must provide to us to support their rate setting process. We believe that by reviewing the process used in setting the rates under a risk contract, we will fulfill our regulatory responsibilities to the fiscal integrity of the Medicaid program and will assure that States have considered all relevant factors in this process. We believe that MCOs, PIHPs, and PAHPs, that contract with States on a risk basis, are better able to determine whether rates are reasonable and adequate, and will do so in deciding whether or not to agree to contract or continue to contract with a State to provide services as part of a Medicaid managed care program.

Comment: A commenter believed that we should acknowledge that actuarially sound rates may vary between MCOs in the same service area.

Response: We acknowledge that rates may differ between MCOs in the same

area for a variety of reasons, but most often when States utilize risk adjustment based upon health status or diagnosis.

Comment: One commenter asked whether the actuarial soundness requirement applies only to capitation rates under an entire contract, or to each rate cell under the contract.

Response: The requirement in proposed §438.6(c)(2)(i) that all capitation rates paid under risk contracts and all risk sharing mechanisms in the contracts must be actuarially sound applies this requirement to all rate cells, as well as the entire contract, and all payments made under the contract. This is a change from the UPL requirement where individual rate cells within the contract could exceed the UPL as long as the entire contract did not exceed the UPL. In order to clarify that the requirement for actuarial soundness applies to all payments, we are replacing the phrase "capitation rates paid" in proposed §438.6(c)(2)(i) with the word "payments."

Comment: One commenter believed that the requirement that rates be “appropriate” for the population and services to be covered under the contract to be too vague, and subject to being interpreted by some to mean covering the full cost of care at billed charges.

Response: The term “appropriate” as used in this paragraph is merely intended to illustrate the requirements that follow in the remainder of §438.6. "Appropriate for populations covered" means that the rates are based upon specific populations, by eligibility category, age, gender, locality, and other distinctions decided by the State. "Appropriate to the services to be covered" means that the

rates must be based upon the State plan services to be provided under the contract.

There is no stated or implied requirement that MCOs be reimbursed the full cost of care at billed charges.

Basic Requirements

Comment: One commenter wanted us to define the term "actuarial basis," as used in §438.06(c)(2)(ii), and provide sample contract language to implement this provision.

Response: "Actuarial basis" as used in §438.06(c)(2)(ii) merely refers to the principles and assumptions used by the actuary in computing the rates in the contract. We do not believe it is necessary to define this term in the text of the regulation.

Comment: One commenter was concerned about meeting the requirements of §438.6(c)(2)(ii), which provides that the contract must specify the capitation rates that are paid. Specifically, the commenter asked if States would be able to submit final rates in an addendum to the contract when the rates are developed after the rest of the contract is implemented.

Response: In answer to the commenter's question, rates must be part of the contract that is approved by us as part of the contract approval process that is a pre-condition for FFP §438.806 in the case of comprehensive risk contracts with MCOs. If rates are not yet agreed upon between the State and the contractor at the time the remainder of the contract is approved, the State could operate under the payment rates that were previously approved by us, although FFP would not be available in

new payment rates until they are approved as well. If the contract is a renewal or extension of a previously approved contract, FFP could be claimed and payments made based the rates in the previously approved contract, until an addendum to that contract with new rates and the supporting documentation required by this section of the regulations is approved.

Requirements for Actuarially Sound Rates

Comment: Some commenters believe that we should clarify that this provision does not preclude States from using additional elements, such as case-rate type payments (for pregnant women or others) and family-based rate cells as long as they are consistent with other requirements.

Response: The requirements in this section are not meant to be all inclusive. States are required either to apply the elements in §438.6(c)(3), or to explain why they are not applicable. Examples of reasons that these elements would not be applicable would include the State's use of case-rate type methodologies or other rate setting methods, that still meet the test for actuarial soundness, or where the rate cells broken down to this level are not large enough to be statistically valid.

Comment: Several commenters wanted us to require States to explain how they have taken into account: potential data inaccuracy due to lack of historical Medicaid managed care data for a new population or service; potential data inaccuracy due to reasonably anticipated under-reporting; and other similar data shortcomings that may be reasonably foreseeable.

Response: We agree with the commenters that these are important factors in

determining payment rates. The adjustments required to smooth data should include adjustments for incomplete data, whether due to incurred-but-not-reported expenditures, delays in claims submission, or other factors. In response to this comment, we are adding data completion factors to §438.6(c)(3)(ii) as one of the required data smoothing adjustments. However, we believe that this is not the only mechanism that could be used to account for unexpected costs of new populations or services, and that these issues are better addressed through risk adjustment or risk sharing provisions in the contract.

Comment: Several commenters wanted us to require States to identify their method for compensating MCOs for changes in obligations imposed on the MCOs during a contract year, so that new requirements cannot be imposed while payment rates remain unchanged.

Response: The terms of a contract must be agreed upon by both parties in order for the contract to be in effect, as required by §438.802(a)(2). One option is for the contract to include a term providing for an increase in payment in the event there are changes in the MCO's obligation (for example, if the contract binds the MCO to cover all State plan services, and services are added to a State plan mid-year). Absent such a provision, the contract would have to be amended in order for payment to be increased to cover new obligations. Any such amendment would have to be approved by us. We will not review and approve those amendments unless both parties, that is, the State and the MCO, PIHP, or PAHP have agreed to the new terms. Thus, we believe that the issue of how changes in contractual obligations are

addressed should be the subject of negotiation between the parties, who are in the best position to agree upon an approach that works in their situation.

Comment: One commenter asked whether States will have the flexibility to take into account their FFS budgets, and managed care budget authority, when developing actuarially sound rates.

Response: We understand the fact that all Medicaid programs are subject to budgets set by the governor and/or the State legislature, and that this obviously must be taken into account in negotiating rates with MCOs, as well as in deciding whether the State can afford to do so. In some cases, there may be insufficient funding to begin or to continue a Medicaid managed care program. We are not in a position to determine if and when a State may have insufficient funding. The Medicaid agency may determine this in advance, or as the result of being unable to attract contractors who are willing to operate a managed care program for the payment rates that the State is able to pay. When contracts are submitted to us for review and approval, the determination of whether adequate funding is available has already been made, in that the State has an agreement with one or more managed care entities and has determined that these entities can meet the contractual obligations to be imposed on them. The managed care entities have determined that the rates they are to be paid are adequate to meet their obligations under the contract. We do not have the authority to change the way States budget for their Medicaid programs in this final rule. We will use our authority to review and approve rates in risk contracts based on the actuarial certification and the documentation provided showing that the

requirements in this section are met.

Comment: Several commenters asked what sources we will accept as base utilization and cost data in determining actuarially sound rates (for example, FFS data, encounter data, MCO financial data) and most of these commenters believed that the rule should specify that these other sources are permissible. Another commenter asked who makes the determination as to whether "costs" are to be determined by FFS history, MCO experience, or other factors.

Response: A State's FFS data would be the best source of baseline data, since they represent the most complete claims history available on the population to be covered under managed care, but only to the extent that the data are recent enough to be valid for this purpose. The fact that there is an increasing number of States that lack recent FFS data to use for rate setting is one of the main reasons that it has become necessary to repeal the UPL requirement. We agree that other sources, such as encounter data, need to be used for this purpose. However, we also recognize that not all States have even begun to collect encounter data, and that not all of those States that are collecting the data have yet developed mechanisms to ensure their validity. States without recent FFS history and no validated encounter data will need to develop other data sources for this purpose. States and their actuaries will have to decide which source of the data to use for this purpose, based on which source is determined to have the highest degree of reliability.

Comment: One commenter believed that experience data used to develop the base period medical cost should only be from the population being rated and

categorized by the rate cells used.

Response: In general, we agree with the commenter that the best source of base period data would be the population to be covered under the managed care contract, but as indicated above, this is not always possible. If the data are not available or usable, States must use other data for this purpose.

Comment: One commenter wanted us to clarify that the phrase "derived from the Medicaid population" at §438.6(c)(3)(i) means those Medicaid beneficiaries enrolled in MCOs. As set forth, this provision would permit the use of State FFS cost data, which may have understated cost assumptions, and inflation data, especially in the area of prescription drugs where MCOs are unable to negotiate prices comparable to those available to the States.

Response: We disagree with the commenter. The phrase "derived from the Medicaid population" means that the source of the base utilization and cost data is the historical utilization and cost data of the Medicaid eligibles to be covered under the managed care contract. These data may be derived from the FFS history, managed care history, or a combination of both. Regardless of the source, adjustments should be made to achieve a degree of predictability for the rates that are developed. The commenter's example of prescription drug costs represents one specific area where the new rate setting rules allow greater flexibility in rate setting than permitted previously. Under the UPL requirement, capitation rates in a contract could not exceed what would have been paid under FFS for the same services provided to a comparable population. For the prescription drug component of a

capitation rate, this amount would have been net of the amount of drug rebates received by the State through its FFS system. Under the new rules, the component of the capitation rate for prescription drugs will not be limited by the UPL.

Comment: Several commenters wanted CMS to require States to provide information on base year costs by primary service category included in the contract, such as, pharmaceuticals, hospital, and physician services, and to clarify that these data will specifically include unit cost and utilization data as separate assumptions, in order to evaluate the adequacy of the rates.

Response: States must report information on base year costs by the primary service category, at a minimum, for the primary services included in the contract. Further, we agree with the commenter that States should use separate assumptions with respect to unit cost and utilization data.

Comment: One commenter believed that the proposed regulation was unclear as to the adjustment factors to be used to make base period data comparable to the Medicaid population in cases in which data specific to the Medicaid population do not exist.

Response: As discussed above, the best source of data for determining base period cost and utilization will have to be determined by the State and its actuaries, subject to CMS approval. States will also need to determine what adjustments are necessary to make data comparable to the Medicaid population if there are no usable Medicaid data available. We would expect these adjustments to be based upon a comparison of the population whose data are used to the State's Medicaid population

in terms such as income, demographics, and historical medical costs. In instances where non-Medicaid data are used, the required actuarial certification will need to include an explanation of the adjustments used to make the data comparable.

Comment: Several commenters suggested that base year costs be trended forward by "medical" inflation, not just "inflation" as stated in the proposed rule, and that we should clarify this in the regulation text.

Response: We agree with the commenters, and in response to this comment have changed the regulation text at §438.6(c)(3)(ii) accordingly. In making this change, we want to emphasize that the rate of medical inflation may be determined from such sources as the medical market basket or the State's historical Medicaid costs.

Comment: Some commenters wanted the administrative adjustment to be expanded to require it to reflect an MCO's cost of complying with Medicaid managed care requirements in such areas as service delivery, reporting, and operational and accountability standards. These commenters argued that administrative costs would have to be significantly increased to comply with the quality provisions and other reporting requirements in this regulation, and that payment rates should reflect these costs.

Response: We agree that the capitation rate should include an administrative adjustment that recognizes administrative costs incurred by the contractor in providing the services to be delivered under the contract. However, we recognize that this adjustment may not necessarily fully compensate the contractor for its

administrative costs under the contract, and potential contractors need to consider proposed payment rates in the aggregate, as to whether or not they will be sufficient to cover both the cost of services and the administrative costs it will incur under the terms of the contract.

Comment: Several commenters asked that we clarify how the limits in proposed §438.6(c)(4)(ii) (regarding an assurance that all payment rates are based only upon services covered under the State plan) apply to the adjustments for inflation and administration in paragraph (c)(3)(ii), and whether we plan to issue guidelines on acceptable adjustment factors and any limits that will be in place.

Response: The intent of this limitation in §438.6(c)(4)(ii) is to prevent States from obtaining FFP for things such as State-funded services for which FFP would not ordinarily be available, by including them in an MCO, PIHP, or PAHP contract. This limitation is extended to the adjustments in paragraph (c)(3)(ii), so that the only administrative costs recognized are those associated with the MCO's, PIHP's, or PAHP's provision of State plan services to Medicaid enrollees. We do not intend to issue specific guidelines on these limits, as we believe that decisions will have to be made on a case-by-case basis.

Comment: Several commenters urged us to specify that risk or profit levels, along with an administrative component, should be included in actuarially sound rates, and that the adjustment requirement in §438.6(c)(3)(ii) is not sufficient to achieve this purpose.

Response: This is another area where we believe all MCOs, PIHPs, and PAHPs

which intend to contract with States must consider proposed payment rates in the aggregate, as to whether or not the payments will be sufficient to cover the cost of all of their contractual obligations and their desired risk and profit levels as well. We do not believe it would be appropriate to establish standards for risk and profit levels.

Comment: One commenter believed that there are many other adjustments that should be applied beyond those listed in the proposed rule, such as adjustments for new procedures or technologies or the addition of new Medicaid benefits.

Response: We agree that there are other appropriate adjustments currently used by States in setting their capitation rates, and will approve those supported by the accompanying certification and documentation as contracts are reviewed and approved. However, we are not mandating any additional adjustments at this time.

For the addition of new Medicaid benefits, however, we believe that the inclusion of any additional Medicaid services during the term of a contract could either be handled through a contract amendment or a contract term that provides for the contingency, subject to CMS approval, subject to CMS approval.

Comment: A number of commenters expressed concerns over the requirements in §438.6(c)(3)(iii) that rate cells be specific to the enrolled population by eligibility category, age, gender, and locality or region. Some commenters asked whether this provision mandates the use of these specific breakouts in developing rate cells, and were concerned that requiring rate cells to be broken down to this level could result in rates in some small cells that are not actuarially sound in States with small populations. Other commenters wanted us to clarify that other types of rate cells,

such as case rate or family-based cells are permissible.

Response: It is our intent that, to the extent possible and practical, rate cells be broken down by these categories. The vast majority of capitation rates in Medicaid managed care contracts currently use these breakouts. However, we recognize that there are valid reasons why this breakout may not be appropriate or possible in a particular State--because of such factors as the size of the population, or because a decision has been made to use another methodology, which still complies with the overall requirement for actuarial soundness. For this reason, the introductory language in §438.6(c)(3) requires States to apply the elements in setting their capitation rates, “or explain why they are not applicable.”

Comment: Several commenters wanted us to specify the type of explanation it would accept for a State that does not use these adjustments, and quantify the burden on States to comply with this provision. One commenter asked whether the explanation could cover an entire managed care program, or whether the State had to separately justify every region or county where the program operates. One commenter wanted us to allow States to use an actuarially appropriate method that may include these cells as appropriate, without requiring the State to justify its approach during each rate-setting process.

Response: We believe that the most obvious reason a State would not use rate cells broken out to this degree would be insufficient numbers of enrollees in any one category for the category to have statistical validity. Another example that would be accepted is the use of a different methodology such as case rates or family-based

cells, provided the methodology still meets the other requirements of this section and has the required actuarial certification. These decisions will be made on a case-by-case basis, and we do not want to limit the flexibility States can have in developing new methodologies by specifying all allowable exceptions in this rule. On the other hand, these rate cells are the most commonly used breakouts in current Medicaid managed care contracts, and we believe that it is not unreasonable to require States to justify other methodologies if that is the approach they decide to use.

We disagree with the commenter that this requirement places any significant burden on States. Most States are already in compliance with the requirement. The remaining States should either be able to provide a simple justification for their alternative methodologies, or need to consider a different approach in setting their capitation rates.

Comment: One commenter wanted us to add a requirement for rate cells by major category of service (that is, inpatient, outpatient, primary care specialist, pharmacy, medical supplies, ambulance and other).

Response: We do not believe that such a requirement would serve a useful purpose. It is important for contracting MCOs, PIHPs and PAHPs to know a payment amount per enrollee, but it is up to the contractor to determine how to allocate that amount at the provider (or service category) level.

Comment: Several commenters felt that the requirements in §438.6(c)(3)(iv) were not clear. This provision required that there be payment mechanisms and assumptions recognizing higher than average medical costs for certain enrollees, for

example, through risk adjustment, risk sharing, or other cost neutral methods. One commenter urged that we clarify that a rate setting method that uses utilization and cost data for populations that include individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims already meets this requirement without additional adjustments, since the higher costs would be reflected in the enrollees' utilization. Another commenter questioned whether this rule requires health status or diagnosis-based risk adjustment, or other risk sharing methods.

Response: The intent of this requirement is that contracts will have some mechanism selected to recognize the financial burden a contractor may incur as a result of enrollees who have much higher than normal health care costs, as a result of either a chronic or acute condition. The fact that the costs of these individuals are included in the aggregate data used for setting rates will not account for the costs to be incurred by a contractor that, due to adverse selection or other reasons, enrolls a disproportionately high number of these persons. Thus, we are requiring some mechanism for risk-sharing or risk adjustment to address this issue. Most MCO contracts currently use either stop-loss, risk corridors, reinsurance, health status-based risk adjusters, or some combination of these approaches. We have not mandated that any particular approach be adopted.

Comment: One commenter asked how we define the terms "chronic illness", "disability," "ongoing health care needs," and "catastrophic claims," as used in §438.6(c)(3)(iv), and whether these are the same individuals categorized as enrollees at risk of having special health care needs, as may be defined by States in

§438.208(b)(3).

Response: The individuals intended to be covered by this requirement would likely include those described as having special health care needs, but would not necessarily be limited to that group. This provision is also intended to address individuals for whom a contractor may incur short-term catastrophic claims, but who may not be defined by the State as having special health care needs. Further, the individuals referred to in this paragraph are identified by their medical costs, while the individuals referred to in §438.208(b) are identified by their medical needs.

Comment: One commenter asked whether we intend to make risk adjustment by health status mandatory in the future, since we have indicated that risk adjustment is an appropriate smoothing factor for individuals with special health care needs, and has contracted to produce a guidance manual for States to use health-status risk adjustment.

Response: The commenter is correct that we support the use of health status risk adjusters as one way of making capitation rates more predictable and accurate, and have contracted for technical assistance for States in developing and using payment systems that are risk adjusted based on health status or diagnosis, and will be providing a guidance manual for States to use for this purpose. However, each State will still need to determine whether it wishes to invest the extensive resources necessary to develop and utilize this type of risk adjustment system. We do not intend to mandate this requirement.

Comment: One commenter wanted us to define the term "appropriate" as used in

§438.6(c)(3)(iv), which refers to appropriate payment mechanisms and utilization and cost assumptions.

Response: As used both here and in the definition of actuarially sound rates, the term “appropriate” means specific to the population for which the payment rate, or in this instance risk sharing mechanism, is intended. This requirement applies to individuals who have health care costs that are much higher than the average.

Appropriate for the populations covered means that the rates are based upon specific populations, by eligibility category, age, gender, locality, and other distinctions decided by the State. Appropriate to the services to be covered means that the rates must be based upon the State plan services to be provided under the contract.

Comment: Several commenters wanted us to define the term “cost neutral” as used at §438.6(c)(1)(ii), and specify how this requirement will be measured. One commenter asked whether a risk sharing model, where the State shares a percentage of excess profits and losses with its MCO, would be considered cost neutral. Several commenters asked whether all of the mechanisms mentioned in §438.6(c)(3)(iv) need to be cost neutral, and whether these mechanisms must be cost neutral over the entire Medicaid program, or just as applied to specific populations.

Response: In using the term “cost neutral,” we are requiring that risk sharing mechanisms recognize the fact that while some enrollees will have much higher than average health care costs, other will have much lower than average costs.

Actuarially sound risk sharing methodologies will be cost neutral in that they will not merely add additional payments to the contractors’ rates, but will have a negative

impact on other rates, through offsets or reductions in capitation rates, so that there is no net aggregate impact across all payments. A risk corridor model, as described by the commenter, where the State and contractor share equal percentages of profits and losses beyond a threshold amount, would be cost neutral. In response to these commenters we have added a definition of “cost neutral” at §438.6(c)(1)(iii).

In response to the other commenters, the cost neutrality requirement must apply to all mechanisms described in §438.6(c)(3)(iv). The mechanism, as set forth in the rate setting methodology, should be cost neutral in the aggregate. How that is determined, however, will differ based on the type of mechanism that is used. A stop-loss mechanism will require an offset to all capitation rates under the contract, based on the amount of the stop-loss. Health status-based risk adjustment may require an adjustment to the capitation rate for all individuals categorized through the risk adjustment system, but the aggregate impact will still be neutral. We recognize that any of these mechanisms may result in actual payments that are not cost neutral, in that there could be changes in the case mix or relative health status of the enrolled population. As long as the risk sharing or risk adjustment system is designed to be cost neutral, it would meet this requirement regardless of unforeseen outcomes such as these resulting in higher actual payments.

Comment: A number of commenters believed that an actuarial certification alone would not be sufficient to justify the payment rates. Some believed that the impact of the adequacy and timeliness of data and the State's budget process must be addressed as well. Other commenters wanted the certification to include enough information for another actuary to independently evaluate the results, including: underlying data, its source and adjustments made; description of rate methodology; documentation of assumptions used; presentation of rates; and expected impact on each MCO's revenues.

Response: We will be looking beyond the actuarial certification of the capitation rates in reviewing and approving rates in risk contracts. The certification is one part of the documentation that will be required, and as described elsewhere in §438.6, there are a number of assurances and explanations that must accompany this certification in order for rates to be approved. We do not believe it is necessary, or in some cases appropriate, for other actuaries to be able to independently evaluate the results and assumptions in setting the rates (other than for our actuaries in cases where their assistance is required). As we stated above, we believe that MCOs, PIHPs, and PAHPs contracting with States on a risk basis must make their own independent judgments of proposed rates based on their own costs of doing business and their understanding of the population to be covered, not necessarily their actuaries' review of the State's actuaries' assumptions and process in setting the rates.

Comment: One commenter was concerned that States or their contracted

actuaries may be required to provide proprietary information to document the assumptions and methodology used to establish the capitation rates.

Response: We do not believe that States will be required to provide any information that is proprietary in nature in order to justify their capitation rates in risk contracts. However, if there are instances where actuaries believe that information their State is required to submit would represent trade secrets or proprietary information, as described in the Freedom of Information Act (FOIA) (5 U.S.C. 552(a)), the information should be identified as such and may be withheld from public disclosure under the provisions of the FOIA.

Comment: One commenter believed that additional documentation should be required, including: eligibility and enrollment trends; provider reimbursement at the Medicaid market level; utilization trends; pharmacy and ancillary costs; benefits in the contract period; and administration.

Response: We believe that the documentation requirements in §438.6(c)(4), along with the other provisions of this rule, will provide sufficient information on which to base decisions to approve or disapprove capitation rates in risk contracts. Thus, we do not believe that the additional documentation suggested by the commenter is necessary.

Comment: A large number of commenters expressed concern over the requirement in §438.6(c)(4)(ii) that payment rates may only be based upon services covered under the State plan. Some of these commenters felt that MCOs need to maintain the flexibility to arrange for, and provide services in the most efficient

manner that meets the needs of the individual, and these alternative services may not be in the State plan. The commenters asked whether this paragraph prohibits States and MCOs from offering additional services or providing services in alternative settings determined to be more appropriate, when these services are not in the State plan. Others asked whether MCOs can still receive payment for these services when they provide them. Some commenters wanted us to allow these costs to be incorporated into the rate calculations.

Response: When a State agency decides to contract with an MCO or other type of managed care entity, it is arranging to have some or all of its State plan services provided to its Medicaid population through that entity. The State has not modified the services that are covered under its State plan, nor is it continuing to pay, on a FFS basis, for each and every service to be provided by the entity. Further, MCOs and other managed care contractors have the ability to do as suggested by the commenters—to provide services that are in the place of, or in addition to, the services covered under the State plan, in the most efficient manner that meets the needs of the individual enrollee.

These additional or alternative services do not affect the capitation rate paid to the MCO by the State. Neither do we believe that the capitation rate should be developed on the basis on these services. This requirement sets forth that principle-- that the State determines the scope of State plan benefits to be covered under the managed care contract, and sets payment rates based on those services. This does not affect the MCOs right, however, to use these payments to provide alternative

services to enrollees that would not be available under the State plan to beneficiaries not enrolled in the MCO.

Comment: Several commenters asked how the cost of non-State plan services, provided as cost-effective alternatives to State plan covered services, can be factored into the development of the capitation rates when a State uses MCO utilization and cost data in setting rates, if under §438.6(c)(4)(ii) rates can only be based upon services covered under the State plan. These commenters believed that States need to be able to incorporate the cost of alternative services in rate calculations. Some commenters suggested that trade-offs should be incorporated into the rate calculation so that the cost of these services can be recognized.

Response: We agree that there must be a mechanism whereby States using MCO encounter data can base utilization costs of actuarially correct rates on non-FFS data. However, actuaries must adjust the data to reflect FFS State plan services only. States cannot use unilaterally contractually required or “suggested” services not part of the State plan (also known as “1915(b)(3) services”) to calculate actuarially sound rates. We are open to suggestions from States and their actuaries, but we will not modify the basic principle that rates be based only on services covered under the State plan.

Comment: One commenter asked whether capitation rates can be adjusted to reflect additional requirements for services like EPSDT and other preventive care that may not have been provided under the State plan in FFS.

Response: Another reason that we decided to replace the UPL requirement

with the requirement for actuarially sound rate setting is to permit States to pay for the amount, duration and scope of State plan services that States expect to be delivered under a managed care contract. Thus, States may adjust the capitation rate to cover services such as EPSDT or prenatal care at the rate the State wants the service to be delivered to the enrolled population. States may use other mechanisms such as financial penalties if service delivery targets are not met, or incentives for when targets are met.

Comment: Another commenter asked if the requirement in §438.6(c)(4)(ii) that payment rates based upon the cost of State plan covered services would prohibit payment for administration, profit, and contingencies, and what effect this would have on the FFP match.

Response: As noted previously, we have clarified the language in §438.6(c)(4)(ii) to indicate that payment may also be made for a contractor's administrative costs directly related to providing Medicaid services covered under the contract. In accordance with §438.812, all costs under a risk contract are considered a medical assistance cost, so there is no impact on FFP.

Comment: A number of commenters raised questions regarding the requirement at §438.6(c)(4)(iii) for a comparison of projected expenditures for a past year to actual expenditures for that year. Several commenters wanted to know what our purpose was in requiring the reporting of year-to-year expenditure differences when evaluating actuarial soundness.

Response: The purpose of this requirement is to provide us with an indicator

of the accuracy of prior year projections and the rate of growth in a State's expenditures under its managed care program, and to provide some direction to reviewers as to whether it may be necessary to look behind the assumptions used by the State in setting the rates. An increase in expenditures that far exceeds the inflation rate in the medical market basket for a given period may warrant further review, as may rates that have been unchanged through several contracting cycles. However, these are not factors that would, in and of themselves, result in the disapproval of proposed rates.

Comment: One commenter requested that we clarify whether the requirement for documentation is an annual requirement or if the information is to be submitted on some other basis.

Response: This information, along with the rest of the documentation required by this rule, would have to be submitted with any new contract, or contract renewal or amendment that included new rates, as part of that required documentation. Thus, the information is not necessarily required to be submitted on an annual basis. States will need to submit the documentation of past and projected future expenditures in time for us to review the expenditure comparison as part of its review of new, renewed, or amended contracts (with revised rates).

Comment: One commenter asked whether the comparison of expenditure data is intended to cover the State's entire Medicaid population, or only that portion which is to be enrolled in managed care during the contract year.

Response: These data should cover expenditures for all Medicaid eligible

beneficiaries in areas where they are or could be enrolled in managed care. Thus, if all TANF eligibles in a part of the State are mandatorily enrolled in managed care, in either a PCCM or an MCO, they would be included in all of past expenditures data and future projections. Also, if SSI eligibles could voluntarily enroll in managed care, data on all SSI beneficiaries (whether the individuals are enrolled in managed care or not) should be included.

Comment: Several commenters believed that we should clarify what is meant by the provision at §438.6(c)(4)(iii), which requires "documenting" the prior year's expenditures as compared to the projected expenditures in the contract year, and asked what type of documentation would be required, and when it would be due. These commenters wanted to know whether we will issue guidelines on the process to be used to project the prior year's expenditures.

Response: We do not believe the provision of these data is either a complex or burdensome process. We require that the State identify that portion of its expenditures in the most recent complete year that are attributable to populations who are or could be enrolled in managed care.

Comment: One commenter asked what flexibility States will have in determining the methodology for making expenditure projections under this provision, and believed States should be able to provide these projections on the basis of either aggregate or per capita expenditures.

Response: While we are not prescribing the methodology for providing this information, we believe that per capita expenditures are the only valid means to

provide the type of information that can be compared from year to year.

Comment: One commenter asked what information States must submit to comply with the requirement at §438.6(c)(4)(iv) to explain incentive arrangements, or stop-loss, reinsurance, or other risk sharing methodologies in MCO contracts.

Response: These risk sharing methodologies can sometimes be very complex. In order for the mechanism to be approved in the contract, the State or its actuary will need to provide enough information for the our reviewer to understand both the operation and the financing of the risk sharing mechanism.

Comment: Several commenters raised questions regarding stop/loss and reinsurance coverage, and asked whether we will require MCOs to obtain stop-loss/reinsurance coverage.

Response: Although a number of States require MCOs to obtain stop-loss or reinsurance coverage, there is no Federal requirement that they do so.

Comment: One commenter asked whether, in cases where the State requires stop-loss insurance, we would require the State to provide a copy of a contract between the MCO and the re-insurer or stop-loss provider to us. Another commenter asked if we would require States to verify the actuarial soundness of MCO stop-loss/reinsurance contracts purchased commercially.

Response: We will not review the actuarial soundness of commercially purchased stop-loss/reinsurance coverage. As mentioned above, there is no Federal requirement that MCOs obtain this coverage, and we will not generally require a copy of the stop-loss/reinsurance coverage contract. However, there are situations

where this may be required, due to unusual circumstances, such as an MCO that is financially unstable.

Special provisions

A number of commenters expressed concerns about the limitation in §438.814 on FFP in contracts with incentive arrangements or risk corridors. These comments are addressed in the portion of the preamble on that section. For purposes of clarity and in order to include these limitations on payment in the same subpart as the other rules governing payments in risk contracts we have moved these provisions from §438.814 to §438.6(c)(5)(ii) and (c)(5)(iii). We have also removed the phrase in §438.6(c)(5)(i), which excepted risk corridors from the requirement for actuarial soundness, since it contradicted other provisions of the regulation.

Comment: Several commenters wanted us to define the terms "risk corridors" and "incentive arrangements" as used in §438.6(c)(5)(ii) and §438.814.

Response: The term “incentive arrangements,” as used in this part, means any payment mechanism under which a contractor may receive additional funds over and above the capitation rates it was paid, for meeting targets specified in the contract. These targets may be for such things as delivery of services such as EPSDT at a specified rate (beyond the level envisioned in the capitation rate), or meeting certain quality improvement standards. Risk corridors are defined as a risk sharing mechanism in which States and MCOs share in both profits and losses under the contract outside of predetermined threshold amount. The amount of risk shared under this arrangement is usually graduated so that after an initial corridor in which

the MCO is responsible for all losses or retains all profits, the State contributes a portion toward any additional losses, and receives a portion of any additional profits. In response to these commenters we have added definitions for “incentive arrangement” and “risk corridor” at §438.6 in paragraphs (c)(1)(iv) and (c)(1)(v) respectively.

Comment: Several commenters questioned the provision in proposed §438.6(c)(5)(iii)(C) that would have required the withholding of payments or other financial penalties in any contract with incentive arrangements, where the incentives are not met. These commenters stated that the requirement did not make sense, since these are two different types of provisions that act independently and serve different purposes.

Response: We agree with the commenter that this proposed provision was confusing and have deleted it from this final rule. Proposed §438.6(c)(5)(iii)(D) has been recodified as §438.6(c)(5)(iv)(C), with subsequent paragraphs similarly renamed.

Comment: One commenter wanted us to clarify what is intended by the requirement in proposed §438.6(c)(5)(iii)(E) (now §436.6(c)(5)(iv)(D) in this final rule), that incentive payments cannot be conditioned on intergovernmental transfer agreements.

Response: The purpose of this prohibition is to prevent incentive arrangements in managed care contracts from being used as funding mechanisms between State agencies or State and county agencies.

Comment: One commenter believes that the requirement in proposed §438.6(c)(5)(iii)(F), (now §436.6(c)(5)(iv)(E) in this final rule) that incentive arrangements be necessary for the specified activities and targets is unclear and a highly subjective determination. The commenter felt that the provision should either be deleted, or alternatively that responsibility for the determination of necessity be placed on the State.

Response: We do not believe that this provision is unclear or highly subjective. A State that decides to use incentive arrangements will have made a determination that they are needed in the contract, and we agree that this should be the State's determination.

Comment: Many commenters objected to the provision in proposed §438.60 prohibiting direct payments to teaching hospitals for graduate medical education (GME) when the hospital's services are provided through managed care. Commenters indicated that this prohibition would disturb longstanding arrangements in many States.

Response: In response to the concerns raised by these commenters, we have modified that section to permit such payments to the extent the capitation rate has been adjusted to reflect the amount of the GME payment made directly to the hospital. We have added new §438.6(c)(5)(v), which requires States making payments to providers for GME costs under an approved State plan, to adjust the actuarially sound capitation rates to account for the aggregate amount of GME payments to be made directly to hospitals on behalf of enrollees covered under the

contract. This amount cannot exceed the aggregate amount that would have been paid under the approved state plan for FFS. We believe this approach addresses State concerns of preventing harm to teaching hospitals and Federal concerns of ensuring the fiscal accountability of these payments. As part of our larger strategy of improving the fiscal integrity of Medicaid payments, we also plan to study existing Medicaid GME payment arrangements and may issue additional policies in the future.

? Services that May Be Covered (Proposed §438.6(e))

The proposed rule at §438.6(e) provided that an MCO, PIHP, or PAHP, contract may cover, for enrollees, services that are in addition to those covered under the State plan.

Comment: One commenter was pleased that the proposed rule expressly provides for MCO contracts to cover services that are in addition to those covered under the State plan, because it will allow them to find new, innovative ways to more effectively treat health problems. A few commenters believed these non-State plan services will allow for cost-effective substitutions for State plan services. However, these commenters question why these non-State plan services cannot be used by the State in the development of payment rates under §438.6(c). One commenter noted that if they are not paid for such non-State plan services it would stifle MCOs in the use of innovative treatment methodologies and technologies. Another commenter questioned how FFP is impacted for these additional services, since they are not allowed to be included in the rate setting methodology under §438.6(c)(4)(ii). This

commenter also asked whether we were requiring payments for these additional services to be actuarially sound and certified as required by §438.6(c).

Response: Those commenters who appear to believe that §438.6(e) allows for payment for additional services that can be provided in lieu of State plan services are not correct. The additional services allowed under §438.6(e) are not included in the calculation of capitation payments. These services may only be offered by an MCO, PIHP, or PAHP paid on a risk basis. This is because these entities would typically use “savings” (a portion of the risk payment not needed to cover State plan services) to cover the additional services in question. Additional services may also be provided for under section 1915(b)(3) waiver authority which allows a State to share savings resulting from the use of more cost-effective medical care with beneficiaries by providing them with additional services. In either case these services are additions to State plan services and are paid for by plans or through shared savings under the waiver program. Since payment is made by the plans or through shared savings, such payments do not have to be actuarially sound and certified. In order to clarify the confusion over this provision, we have added the phrase, “although the cost of the services cannot be included when determining the payment rates under §438.6(c).” Further, for a discussion of the prohibition against including non-State plan services in setting capitation rates, see the preamble discussion of §438.6(c)(4).

? **Compliance with Contracting Rules (Proposed §438.6(f))**

This section requires all contracts under this subpart to comply with all

Federal and State laws and regulations and meet all requirements of this section.

Comment: We received one comment supporting the provisions regarding compliance with applicable Federal and State laws and regulations found in §438.6(f).

Response: We are retaining the provisions supported by the commenter in this final rule, and appreciate the commenter's supportive comments.

? **Inspection and audit of financial records (Proposed §438.6(g))**

This section of the proposed rule required that the financial records of contractors and subcontractors be available for audit and inspection.

Comment: One commenter supported the explicit requirements of §438.6(g). The commenter noted that without access to financial arrangements with subcontractors, it is difficult to track whether rates are sufficient to ensure that children have access. The commenter urged us to make this information publicly available.

Response: We are not imposing a requirement on States to make these financial data public, nor will we establish a mechanism to do so at the Federal level. However, under §438.10(g) (3) enrollees are entitled to obtain information on the structure and operations of their MCO or PIHP, and for States with mandatory managed care under section 1932(a)(1), §438.10(i)(3)(iv) provides that beneficiaries are entitled to receive quality and performance indicators on the MCOs and PIHPs available to them. We believe that this type of information has more value to Medicaid beneficiaries than the financial data required by this section.

? **Advance Directives (Proposed §438.6(i))**

Proposed §438.6(i) requires that all MCO and PIHP contracts comply with the requirements of §422.128 (M+C rules) for maintaining written policies and procedures for advance directives, and reflect changes in State law within 90 days.

Comment: One commenter asked for the definition of the term "advance directive" as used in §438.6(i).

Response: The provisions on advance directives are cross referenced to the more detailed M+C rules in §422.128, which are further linked to the definition of the term in §489.100. As defined in §489.100, "advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

Comment: One commenter was concerned that providing all adult enrollees with written information on advance directive policies, and including a description of applicable State law changes, will cause MCOs to duplicate information and develop documentation systems that will add unnecessary cost and an administrative burden, thereby reducing efficiency of providing health care.

Response: Because section 1903(m)(1)(A) of the Act requires MCOs to provide information on advance directives to enrollees, we do not have the authority to eliminate or modify the advance directives provision for MCOs under §438.6(i).

Comment: Another commenter believes the advance directive requirements should be expanded to all managed care enrollees and not just for those enrollees in

MCOs and PIHPs. The commenter believes that beneficiaries have the same right to make informed choices about outpatient treatments as those beneficiaries do about inpatient treatments.

Response: Section 489.102(a) identifies those providers required to comply with advance directive requirements. That section includes providers that could be participating in a PAHP network, including hospital outpatient providers and home health agencies. Therefore, we agree with the commenter that advance directives should apply to PAHPs if their network includes any of the providers that are listed in §489.102(a). We have added a new §438.6(i)(2) to include this requirement.

? **Additional Rules for Contracts with PCCMs (Proposed §438.6(k))**

This section proposed new rules found in section 1905(t)(3) of the Act which specify the requirements that must be included in contracts with primary care case managers.

Comment: One commenter felt that the contract requirements for PCCMs were too minimal, and that patients in PCCM programs should have rights of access, coverage, information, and disclosure that are as strong as those that apply to MCOs, PIHPs, and PAHPs.

Response: The contract requirements for primary care case managers in proposed §438.6(k) largely mirror the language set forth in section 1905(t)(3) of the Act, which was added by section 4702 of the BBA. The BBA is clear in setting forth which contracting requirements should be placed on primary care case managers, which should be placed on MCOs, and which apply to all MCOs, PHPs, or PCCMs. PCCM contracts must include those requirements set forth in section 1905(t)(3) as

well as any additional requirements in section 1932 of the Act that apply to them. For example, a PCCM must meet the information requirements set forth in §438.10 that apply to it. We also have applied access, coverage, and information requirements to primary care case managers where applicable. Where the BBA specifies that requirements apply to MCOs, such requirements are not applicable to PCCM contracts. However, where a PCCM is paid on a capitated basis, the PCCM would meet the definition of a PAHP and would also be subject, by regulation, to all PAHP requirements.

Comment: One commenter is concerned that the requirement in §438.6(k)(2) that “restricts enrollment to recipients who reside sufficiently near one of the manager’s delivery sites to reach that site within a reasonable time using available and affordable modes of transportation” does not take into consideration the special circumstances and characteristics of frontier states. The commenter wanted us to clarify what is a “reasonable” time in frontier states where the nearest provider may be more than 100 miles from the beneficiary, and very few locations have any public or commercial transportation available. The commenter asked whether this prohibits a recipient from choosing a provider who is further away, which could result in decreased beneficiary satisfaction and choice. The commenter suggests a standard based on “normal and customary” practices that would allow for a frontier state to better serve its population.

Response: We do not believe that this requirement imposes any unreasonable burden on frontier states as suggested by the commenter. The

requirement in proposed §438.6(k)(2), that beneficiaries be able to access care within reasonable time using affordable modes of transportation, is derived from statutory language in section 1905(t)(3)(B) and cannot be changed. However, states have the flexibility to determine their own standards for reasonableness based on normal distance and travel times in the area, the needs of the beneficiaries, provider availability, and the geographic uniqueness of the State. One example, as noted in the preamble of the proposed rule, is the 30-minute travel time standard that many States have adopted for urban areas. Other States have established 10 to 30 mile distance standard, depending on specific circumstances within the area of the State to be served. We have consistently permitted States to develop their own standards, based upon customary treatment patterns in their unrestricted FFS programs, in the approval of section 1915(b) waiver programs.

While we require States to develop their PCCM programs so that enrollees should not have to travel an unreasonable distance beyond what is customary in the State's unrestricted FFS program, we encourage States, to the extent practical, to make exceptions for beneficiaries who request to travel further than the time and distance standards set by the State, for such reasons as a desire to maintain an ongoing relationship with a particular participating provider. Section 438.6(k)(2) would not prohibit such exceptions, provided the beneficiary was aware of his or her options and could make an informed choice of PCCM.

? **Subcontracts (Proposed §438.6(l))**

This proposed rule requires all subcontractors to fulfill the requirements of §438.6

that are appropriate to the services or activity delegated under the subcontract.

Comment: One commenter asked for clarification about whether the CMS Regional Office must also review and approve all subcontracts since §438.6(l) requires that all subcontracts must fulfill the requirements of §438.6, and §438.6(a) requires the CMS Regional Office to review and approve all MCO, PIHP, and PAHP contracts.

Response: The requirement for Regional Office review of contracts in §438.6(a) only pertains to contracts between States and MCOs, PIHPs, and PAHPs, but not to subcontracts between any of these entities and their subcontractors. As noted above, §438.6(l) only requires compliance with provisions in §438.6 that are "appropriate" to the service or activity covered under the subcontract, and we do not believe that such review would be appropriate to the services or activities delegated under the subcontracts, or a worthwhile expenditure of our resources. Our focus is on the contractual relationship between the State and the MCO, PIHP, or PAHP as the primary contractor, as required by section 1903(m) of the Act, with respect to MCOs. The primary contractor is the entity that is obligated to comply with all provisions of the contract, whether it uses subcontractors in order to do this or not. The use of subcontracts does not in any way alter the primary contractor's responsibilities, obligations, or authority under the contract.

? **Choice of Health Professional (Proposed §438.6(m))**

This section sets forth the right of an MCO enrollee to choose his or her health professional to the extent possible and appropriate.

Comment: One commenter suggested that the regulations should specify that MCOs must let enrollees choose their primary care provider from among all qualified participating providers, including specialists. The commenter also suggested that when an enrollee is unable to be linked to their first choice of primary care provider, the MCO should have a mechanism for linking the enrollee to that provider when the provider becomes available.

Response: Section 438.6(m) permits an enrollee to choose his or her health professional to the extent possible and appropriate. This would include the selection of primary care providers participating in the MCO, PIHP or PAHP network, unless they were already at capacity. We do not believe it is necessarily appropriate for specialist to act as primary care providers in every instance. Primary care is defined in §438.2, and does not describe the range of services provided by many specialists. We believe that the decision on whether a specialist is the appropriate PCP for any enrollee should be left to the MCO, PIHP, PAHP, and/or the State to be determined on an individual basis. If an enrollee is unable to be placed with their first choice of primary care provider, they may continue to check on that provider's availability and change PCP when it becomes possible to do so. We do not believe this change is necessary in the regulation text. However, we are removing reference to MCOs, since this requirement applies to PIHPs and PAHPs as well under §438.8.

4. Provisions that apply to PIHPs and PAHPs (Proposed §438.8)

This section specifies which provisions of this rule apply to PIHPs and which apply to PAHPs.

Comment: Many commenters believed that the same requirements should apply to both PIHPs and PAHPs, and several suggested that both types of PHPs should be subject to the same requirements as MCOs. These commenters argued that both types of entities cover an increasingly large portion of the Medicaid population, that requirements for an adequate and appropriate network are just as relevant and necessary for dental and transportation providers as for MCOs, that children with special health care needs require specialized care regardless of the scope of services their managed care contractor provides, and that any plans that provide any type of medical care should be required to comply with the protections in the BBA, such as network adequacy, credentialing, and grievance rights.

Several other commenters suggested that even plans providing non-medical services, such as transportation should be required to have an adequate network, provide services timely, and have a mechanism to resolve complaints.

Another commenter suggested returning to a single set of requirements for PHPs, but accommodating PHPs covering a more limited array of services by permitting them to deviate from standards that are not applicable to the entity or services it provides or allow additional time to come into compliance.

Other commenters expressed support for the distinction in requirements between PIHPs and PAHPs and the flexibility in the rule to determine how to most appropriately regulate PAHPs.

Response: As stated above in the discussion regarding definitions at §438.2, we believe that there are clear differences in terms of the degree of financial risk,

contractual obligations, scope of services, and capitation rates paid to these different types of entities, and that the scope of rules that apply to these entities under this regulation should reflect these distinct differences. However, in considering the provisions of the proposed rule and the issues raised by commenters, we agree that there are additional provisions of this regulation that should apply to PAHPs and have modified the requirements of the final rule to implement these changes. In §438.8(b), we have added the following requirements to PAHPs: advance directives where a PAHP has a network of providers that includes either hospital outpatient departments or home health agencies (see the response to comments on §438.6(i) advance directives), all of subpart C on Enrollee Rights, and designated portions of subpart D on Quality Assessment and Performance Improvement. We have added new information requirements specific to PAHPs in a new paragraph (h) in §438.10 (with the existing paragraph (h) renamed paragraph (i)). Finally, at §438.6(b)(7), we have reaffirmed a PAHP enrollee's right to a fair hearing under §431.220. We believe that with these changes, we have maintained an appropriate level of regulatory requirements for these entities and provided the necessary degree of flexibility for States to implement these programs and impose any additional requirements States determine to be necessary. In addition, we believe we have provided the necessary level of beneficiary protections for these programs, including network adequacy (where applicable), provider credentialing, and appeal rights. We do not believe that applying additional provisions to PAHPs would be appropriate based on the scope of services they provide and the capitation rates they are paid in

comparison to PIHPs and MCOs.

Comment: Several commenters raised specific concerns about PAHP rules governing prepaid dental plans. Some commenters indicated that Medicaid dental patients need patient protections like MCO enrollees, since oral and systemic health are both integral to overall health, and should have the same patient protections.

Another commenter asked whether MCO or PAHP rules apply to MCOs that subcontract for dental care. Several commenters were concerned that dental services are provided as part of MCO contracts and FFS as well as by prepaid dental plans, and PAHP dental enrollees should have the same protections as MCO enrollees receiving dental care.

Response: We agree with the commenters regarding the importance of dental health and that beneficiary protections are an important requirement for dental PAHPs, particularly the requirement for network adequacy. One reason that States use prepaid dental plans is because of the lack of dental providers who provide care under FFS. Guaranteeing an adequate network in a dental PAHP will provide Medicaid beneficiaries access to dental care that is often otherwise unavailable.

The determination as to which rules apply to any service or delivery system is the identity of the entity that contracts with the State. Thus, in situations where an MCO has a contract with a State, MCO rules apply to services furnished by the MCO or its sub-contractors, including a subcontracting pre-paid dental plan. Where a PIHP or PAHP contracts with the State, PIHP or PAHP rules apply respectively.

Comment: Several commenters objected to the requirements imposed on

PIHPs. They believed that the proposed requirements were unclear, ambiguous, and burdensome, and would require the State to spend money on administrative expenses rather than patient care. These commenters felt that the proposed requirements were targeted to a medical model and did not take into account behavioral health services, such as mental health and substance abuse or rehabilitation models. They pointed out that PIHPs only authorize and pay for community psychiatric hospital beds and not all inpatient hospital care, and thus should not be subject to MCO requirements.

Response: We acknowledge that this rule will impose many new requirements on PIHPs, just as it imposes new requirements on MCOs and PAHPs. Most of the new rules imposed on MCOs were derived from the BBA. Prior to the BBA, PHPs were subject, under Part 434, to most of the rules governing Medicaid-contracting HMOs. We believe that the Congress determined that additional costs and administrative burden were justified in order to provide sufficient protections for beneficiaries enrolled in MCOs. We believe that these same considerations apply to PHPs that provide inpatient services. In addition, we believe that beneficiaries in need of mental health and substance abuse services may be particularly vulnerable, and need these protections more than some other healthier Medicaid beneficiaries.

Comment: One commenter apparently believed that while PCCMs covering some or all of the following services were subject to PCCM requirements (case management, durable medical equipment, EPSDT, family planning, hearing, home health care, immunizations, laboratory, outpatient hospital, pharmacy, physician, transportation, vision, and x-ray) a managed care plans covering a subset of these

services would be exempt from all enrollee safeguards and quality and integrity requirements.

Response: It is true that the referenced services can be furnished through a PCCM arrangement, under which the primary care case manager provides physician services and case management, and has the responsibility to refer or prior authorize these other services for their enrollees. It is also true, that in such a case, the PCCM requirements, and any requirement that applies to a "managed care entity" (both MCOs and PCCMs) would apply in this case. However, it is also true that a managed care plan that provides a subset of these services would be subject to enrollee safeguards and quality and integrity requirements, as an MCO or a PAHP. An entity that was at risk for the full scope of services described by the commenter (or any subset of three or more of the services described in §438.2 in the definition of comprehensive risk contract) would be considered an MCO, even though inpatient services were not being provided. If the "subset of services" did not trigger the definition of comprehensive risk contract, the entity would still be regulated as a PAHP, and PAHPs are not exempt from all enrollee safeguards and quality provisions.

Comment: Several commenters wanted us to impose PIHP requirements on prepaid providers of home and community-based services (under a section 1915(c) waiver) in order to assure that beneficiaries in programs that maximize community-based care and minimize the need for institutionalization will have sufficient protections. One commenter contended that the Supreme Court's decision in

Olmstead v. L.C., and the President's New Freedom Initiative, dictate that all provisions in the proposed rule that would improve or ensure access to care must be provided to those who need community-based care in order to reside outside of institutions. Other commenters believed that PIHP rules should not apply to home and community-based services, since the rules could discourage participation of these needed providers, and take away State and local discretion to impose, waive, or adjust requirements as best determined at that level.

Response: Home and community based service providers by definition do not provide "inpatient" care, and accordingly would not meet the definition of PIHP. In light of our decision, discussed above, to impose additional requirements on PAHPs, we believe that we have provided sufficient beneficiary protections for PAHPs that provide home and community based services, while at the same time accommodating the latter commenter's concern about requirements discouraging participation. In so doing, we believe that we are helping to implement the Olmstead v. L.C. decision and the President's New Freedom Initiative, and to ensure access to community-based care with appropriate enrollee protections and quality assurance.

Comment: One commenter felt that all PIHPs and PAHPs should be subject to sanctions if they do not comply with the regulations.

Response: The sanction authority enacted by the Congress in the BBA is limited to MCOs. We do not believe we have authority, by regulation, to authorize States to impose civil money penalties on PAHPs or PIHPs. However, States may cover PIHPs and PAHPs under their own State sanction laws, and we encourage

States to do so whenever they believe it is necessary.

Comment: One commenter wanted us to add a provision to exempt MCOs with less than 500 members from the same requirements from which PAHPs are exempt.

Response: Because PIHP and PAHP requirements are based on broad on the authority in section 1902(a)(4) of the Act, we have the discretion to impose those requirements on PIHPs and PAHPs that we determine to be appropriate through regulations. However, requirements for MCOs are specified in sections 1903(m) and 1932 of the Act, and are not subject to modification by regulation on the basis of the number of an MCO's enrollees.

5. Information Requirements (Proposed §438.10)

Proposed §438.10 set forth the requirements that apply to States, MCOs, PIHPs, PAHPs, PCCMs, and enrollment brokers concerning the provision of information to enrollees and potential enrollees. Paragraph (a) defined the terms used in this section. Paragraph (b) set forth the basic rule that all information provided must be in a manner and format that may be easily understood. Paragraph (c) established rules regarding language. Paragraph (d) specified the format for information and that alternative formats must be available. Paragraph (e) described information requirements for potential enrollees. Paragraph (f) set forth the general information requirements for enrollees of all MCOs, PIHPs, PAHPs, and PCCMs. Paragraph (g) contained specific information requirements for MCO and PIHP enrollees. And paragraph (h) set forth the special rules required of States with

mandatory enrollment under the State plan authority in §438.50.

General Comments on §438.10

Comment: Some commenters appreciated the clarity and content of this section, and stated that they did not believe the provisions were too prescriptive. By contrast, another commenter contended that the requirements were too prescriptive, and would be difficult to meet even for a non-Medicaid population. This commenter believed this section as a whole did not take into consideration the nature of frontier States. The commenter recommended reducing the Federal role in the provision of information to beneficiaries, and letting States have the discretion to determine what is most appropriate.

Finally, one commenter believed that the proposed rule did not ensure that enrollees would receive adequate information to understand their rights and responsibilities, and that it failed to provide potential enrollees with enough information to make an appropriate decision. The commenter believed this is especially true for individuals with chronic health conditions, who often see numerous medical professionals. The commenter asserted that these beneficiaries must have adequate information to make the best decision to ensure that their health needs can be met within a plan's network.

Response: We believe the proposed rule achieves an appropriate balance between ensuring potential enrollees and enrollees have sufficient information, and giving the State flexibility in implementing the regulation. We appreciate the comments in support of the clarity of the proposed rule, and the comment that it

contains an appropriate level of prescriptiveness. For frontier areas, enrollees there also need a minimum set of information to navigate a managed care program. We believe the regulations are flexible enough to accommodate the unique circumstances of rural and frontier areas, and have identified specific instances in our responses to subsequent comments. Finally, we believe the minimum information required in the proposed rule is sufficient for all potential enrollees and enrollees, even those with disabilities or chronic illnesses. There are areas where information that might be especially useful for this population is available upon request instead of provided automatically (for example §438.10(d) on alternative formats, §438.10(e)(2)(ii)(D) on summary provider information, and §438.10(g) on information on plan structure and operations), but the final rule makes clear that these enrollees and potential enrollees must be informed of how and where to get this information.

Definitions (Proposed §438.10(a))

Proposed paragraph (a) set forth definitions of "potential enrollee" and "enrollee."

Comment: One commenter supported the definitions of "potential enrollee" and "enrollee." Another commenter, however, felt that the regulation needs to clarify who an enrollee is in the case of a specialty plan. For example, in the commenter's State, all Medicaid recipients are required to receive mental health services from certain plans, but the State does not give information about mental health services until an individual actually receives services. This commenter

recommended the State or plan should provide minimum general information about the plan and what services are provided at the time of initial enrollment in the plan, and provide more detailed information when the beneficiary first contacts the plan to inquire about services available.

Response: We believe that the definition of enrollee is appropriate for any managed care program, including mental health managed care. We believe that the regulation's flexibility on providing certain information in summary format meets the commenter's first suggestion. We disagree with the suggestion to delay providing the full set of required enrollee information to the point in time when an enrollee requests services. This fails to provide adequate information to enrollees, and could be a barrier to care for enrollees who are unsure of what services the plan provides and how to access those services. We acknowledge that this will result in increased burden for States such as those in which the commenter resides where there is a single PIHP per service area in which every beneficiary is automatically enrolled upon determination of Medicaid eligibility. Some of the anticipated burden could be reduced by providing the required potential enrollee and enrollee information at the same time.

Mechanism To Assist Understanding (Proposed §438.10(b))

As noted above, proposed paragraph (b) set forth the basic rule that all information provided must be in a manner and format that may be easily understood.

Comment: Numerous commenters believed that the proposed basic rule at §438.10(b) failed to require States to have a mechanism to help enrollees and

potential enrollees understand the managed care program, and failed to require MCOs, PIHPs, and PAHPs to have a mechanism for enrollees and potential enrollees to understand the requirements and benefits of the plan. Several argued that beneficiaries need to have the ability to get information from a variety of resources, not just written material. They felt that a mechanism was needed to ensure that enrollees and potential enrollees have information necessary for informed decisions. Some commenters believed that the lack of such a source of assistance would have a harmful impact on persons with disabilities, especially mental retardation and other cognitive impairments. One commenter urged that such a mechanism be family-friendly. Several commenters noted that such a mechanism was included in the Bipartisan Patient Protection Act (HR 2653), CMS' Report to the Congress entitled "Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care," and the President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry.

The commenters recommended requiring States to have a mechanism for potential enrollees and enrollees to understand the State's managed care program. Examples included a toll-free hotline, ombudsman, and other types of consumer assistance. Many of the commenters further recommended requiring that MCOs, PIHPs, and PAHPs have a mechanism to help potential enrollees and enrollees understand the requirements and benefits of the specific plan. Two commenters recommended the plan's mechanism need only be provided for enrollees, not potential enrollees.

Response: We agree with commenters that written information may not be sufficient for potential enrollees and enrollees to understand a managed care program. In response to these comments, we have amended §438.10(b), by adding paragraphs (b)(1) and (b)(2) to require that States, MCOs and PIHPs have mechanisms in place to help beneficiaries that need such help to understand the managed care program, and plan requirements and plan benefits. We believe that it is not necessary to separately require PAHPs and PCCMs to have such mechanisms, as information on such plans could be addressed by the State's mechanism. We will require the mechanism to be available to both potential enrollees and enrollees, especially given that much of the required potential enrollee information need only be provided in summary format. We believe, however, that the State and plans should be given the discretion and flexibility to provide the mechanism most appropriate to their situation, so we are not specifying the type of mechanism that must be in place.

Comment: One commenter requested that health plans be made aware of their responsibility to respond to a beneficiary's questions in a timely manner.

Response: We agree that plans should respond in a timely manner, and expect them to do so. However, we do not believe that it is necessary to specifically provide for this in regulation text.

Comment: Numerous commenters noted that the basic rule requires that only certain information be presented in a manner and format that is easily understood. They objected that this did not appropriately safeguard the rights of beneficiaries.

The commenters believed that limiting the requirement to only certain material fails to give beneficiaries with limited English proficiency sufficient information. Some expressed concern that this could also violate section 1932(a)(5)(A) of the Act, which the preamble to the proposed rule characterized as requiring “all written information be provided in an easily understood language and format.” Commenters recommended expanding the requirement to include “all” materials. On the other hand, there was one commenter who agreed with the limitations on which materials must meet the criteria.

Response: While we share the commenters concern that all material should be in a manner and format that is easily understood, this section of the regulations is derived from section 1932(a)(5)(A) of the Act which specifically requires that responsible parties “ provide all enrollment notices and information and instructional materials...in a manner and format which may be easily understood.” Thus, notwithstanding the unqualified language in the preamble, section 1932(a)(5)(A) of the Act limits the type of information covered by its provisions. However, in addition to the specific requirements that apply to enrollment notices and information and instructional materials contained in this section, provisions of the regulation governing information on enrollee rights, provider enrollee communications, marketing, grievances and appeals, and termination of MCOs and PCCMs all reference the requirements of this section. We believe that this extends the requirements for an easily understood language and format to virtually all written material provided to potential enrollees and enrollees. Thus, we do not agree that it

is necessary to revise the regulation in response to this comment.

Clarifying Responsible Entity (Proposed Rules §438.10(b) and §438.10(f))

As noted above, paragraph (b) sets forth the basic principle that information must be provided in a form that is easily understood. However, it does not set forth which entities are obligated to provide what specific information. This also is the case with respect to one paragraph in paragraph (f), which sets forth the general information requirements for enrollees of all MCOs, PIHPs, PAHPs, and PCCMs. The introductory paragraph to paragraph (f) refers to information being made "available."

Comment: Numerous commenters objected to the fact that the text of the "basic rule" in §438.10(b) does not identify who is responsible for providing information to potential enrollees and enrollees. One commenter asserted it is not enough for §438.10(f) to require only that information be made "available" to enrollees, because this creates what the commenter believed to be a needless barrier to ensuring beneficiaries have the information they need. Finally, many commenters expressed concern that §438.10(f)(6) (regarding required information for enrollees) did not specify who was responsible for providing required information to enrollees. Some of these commenters recommended clarifying that the State is responsible for providing required information to enrollees, and that the State can delegate this responsibility to the health plan. Other commenters suggested clarifying that the plan is responsible for providing required information, and that the State is responsible for ensuring compliance.

Response: While the text in §438.10(b) setting forth the "basic rule" does not itself identify who is responsible for providing what information to potential enrollees and enrollees, we believe that other provisions of the regulations text make this clear. Specifically, §438.10(e)(1) specifies that the State or its contracted entity is responsible for providing required information to potential enrollees; §438.10(f), with one exception discussed below, specifies which entity or entities is responsible for providing specified information; §438.10(g) specifies that MCOs and PIHPs are responsible for providing information specific to those types of programs; §438.10(h) specifies that the State or a PAHP must provide information on PAHPs; and §438.10(i); specifies the State is responsible for providing certain information required under a State plan amendment.

Within §438.10(f), each of the paragraphs specifies a responsible party, except, as commenters note, paragraph (f)(6). While §438.10(f)(3) specifies who is responsible for providing the information in §438.10(f)(6), we agree that §438.10(f)(6) – read alone -- is unclear. We are revising §438.10(f)(6) to specify the State or at its discretion, its contracted entity, the MCO, PIHP, PAHP, or PCCM, is responsible for providing required information to enrollees. We will also conform the language identifying responsible parties in §438.10(f)(4) and §438.10(g) with the language used in other paragraphs. Finally, while each paragraph in §438.10(f) requires the provision of certain information, in response to this comment, and for consistency, we are revising the introductory paragraph to replace “made available” with “provide.”

Prevalent Languages (Proposed §438.10(c))

Proposed paragraph (c) required that information be made available in prevalent languages.

Comment: One commenter supported basing the determination of whether a language is prevalent in the potential enrollee and enrollee population, rather than the State's population as a whole. The commenter stated this more appropriately targets those who would use information being translated.

By contrast, a few commenters noted that proposed rule only requires States to identify prevalent languages, not all languages spoken by potential enrollees and enrollees. They asserted this is a weak standard, and disproportionately harms community health centers, which serve a disproportionate share of people with limited English proficiency. The commenters recommended the State be required to identify all languages spoken in State, not just prevalent languages.

Response: We agree with the first commenter that the proposed rule's focus on the enrollee and potential enrollee population in the state is most effective. We disagree with the latter commenters that the proposed "prevalent languages" standard is weak. The proposed rule conforms with the Office for Civil Rights' "Policy Guidance title VI Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency." Specifically, that Guidance suggested that written material should be translated into regularly encountered languages other than English spoken by a significant number or percentage of the population eligible to be served.

Comment: One commenter noted that there is generic (versus plan-specific) information in §438.10(f)(6) that must be translated into prevalent languages. The commenter believed it would be wasteful and inefficient to require each plan to translate it, and any variation in this generic language across plans would be confusing to beneficiaries. The commenter recommended requiring States to make translations of generic information available to plans.

Response: Nothing in the proposed rule would prohibit the State from translating material that is not plan specific. However, we believe States should have flexibility on whether to adopt this approach.

Comment: One commenter noted that the proposed regulatory provisions placed sole responsibility for identifying prevalent languages on the State. In the commenter's State, there is a model in which plans are required to identify the prevalent languages spoken by their enrollees, and forward that data to the State. The commenter stated this allows the plan to concentrate on the language needs of their membership; the State then combines its data with plans' data for a more accurate picture of non-English languages spoken. The commenter recommended flexibility in this area so that the maximum amount of prevalent language data can be collected at all levels of contact with the enrollee.

Response: We believe the proposed rule provides the flexibility this commenter seeks. Specifically, §438.10(c)(1) requires the State to "establish a methodology," but gives States the discretion on what the actual methodology is. It would not preclude the methodology described by the commenter.

Comment: Numerous commenters expressed concern that the definition of “prevalent” at §438.10(c)(1) was based on prevalence among the enrollee and prospective enrollee population at a Statewide level, not a service area level. They observed that if beneficiaries with limited English proficiency are concentrated in a few areas, there may not be enough to meet statewide prevalence threshold. One commenter stated this was especially an issue in more populated States.

The commenters recommended basing prevalence on service area, not a statewide threshold. One recommended it be based on geographic area, as stated in the preamble to the proposed rule. Another commenter recommended the rule define service area. Still others urged the rule go further, and specify a threshold of 5 percent within localized area. A few proposed the rule set a threshold of 10 percent or 3,000 in a service area, with additional specifications if there are 5 percent or less, as well as under 100 potential enrollees or enrollees. Finally, a commenter suggested that if the State does not identify prevalent languages by service area, that plans be required to do so.

Response: We appreciate the commenters’ point regarding languages that may be prevalent at a service area level but not meet a statewide threshold. However, we believe the proposed rule takes this into account. Specifically, §438.10(c)(2) requires the State to “Provide written information in each prevalent non-English language.” However, §438.10(c)(3) requires each MCO, PIHP, PAHP, and PCCM to make its written information available in the prevalent non-English languages in its particular service area. For potential enrollees and enrollees who

primarily speak a non-English language that is not prevalent, the mechanism we are requiring in response to a comment on §438.10(b) will provide them an avenue for obtaining needed information.

Comment: One commenter contended that requiring States to identify prevalent languages is administratively burdensome and costly. Another commenter found the language requirements problematic, especially for rural States, and believed they would create additional costs for State and plans. Finally, a commenter noted the difficulty of consistently producing materials in prevalent non-English languages in a timely fashion. On the other hand, numerous commenters supported the proposed rule requiring a methodology to identify prevalent non-English languages, and provision of written information in those languages.

Commenters who had concerns about the prescriptiveness of the proposed language requirements recommended more flexibility in the language requirements, including allowing States the flexibility to determine if additional language versions of written information are necessary.

Response: The OCR Guidance we referenced in our earlier response makes clear that all entities that receive Federal financial assistance from the Department of Health and Human Services, either directly or indirectly, must provide meaningful access to its services for beneficiaries with limited English proficiency. This includes providing translated versions of vital documents into non-English languages regularly encountered in the eligible population. The Guidance provides suggested methodologies for identifying prevalent languages, which may be of use to States

that do not yet have a methodology in place. It may be that in a rural State, there are no non-English languages that would meet a prevalence test. In those instances, States must still arrange for oral interpretation and have a mechanism (see comment and response on §438.10(b)) to assist non-English speaking beneficiaries to understand written materials that are not translated.

We believe the proposed rule gives considerable discretion to States in what methodology they use.

Comment: Several commenters expressed support of the proposed rule's reinforcement of existing language requirements under title VI of Civil Rights Act of 1964. Others suggested specifically referencing in the rule guidance issued by the Office for Civil Rights, since it applies to States and plans receiving Federal funding under Medicaid.

Response: We appreciate the commenters' support on this issue. We have disseminated the Guidance to States via a State Medicaid Director letter dated August 31, 2000, and it is also available on our website. We do not believe it necessary to specifically reference the OCR Guidance in the regulation.

Comment: Numerous commenters noted that the definition of "prevalent" does not define what constitutes a "significant number or percentage." They believe this is not sufficient guidance, and that there is no compelling need for States to have discretion. On the other hand, a few commenters expressed support for giving States the discretion to define prevalent.

The commenters concerned about lack of guidance uniformly recommended

the final rule establish a minimum threshold. Recommendations included defining prevalent as 10 percent or 3,000; incorporating OCR guidance on “safe harbors,” and using a threshold of 5 percent in a localized area and a Statewide level of 5 percent as well.

Response: We believe that the language and format requirements are essential elements for ensuring that enrollees and potential enrollees receive the information necessary to make an informed choice and access benefits. While we believe they are essential elements, we also continue to believe that the best methodology for determining the prevalent language spoken by a population in a service area may differ from State to State and therefore we will not be modifying the regulation to mandate a specific methodology. We also note that the OCR policy guidance referenced above gives further examples and guidance on meeting individuals’ language needs.

Comment: One commenter noted that §438.10(c)(2) requires States to provide written information in each prevalent language, but §438.10(c)(3) only requires plans to make translated written material available. The commenter believes that this seems to suggest that unlike plans, States cannot simply respond to a request and instead must actually ensure it distributes translated materials to each beneficiary with limited English proficiency. The commenter stated this would be an onerous requirement, and recommended instead that latitude be given to States to respond to an inquiry.

Response: We agree that the wording could be construed to required

different levels of effort between the State and plans. In response to this comment, we are revising §438.10(c)(2) to clarify that States need only make translated materials available. We note that §438.10(c)(5) still requires States and plans to notify enrollees and potential enrollees that translated materials are available and how to obtain them.

Comment: One commenter noted that the proposed rule required States and plans to identify beneficiaries with limited English proficiency. However, the commenter believed that individuals with limited English proficiency should be able to self-identify and receive appropriate written and oral communication.

Response: We agree that beneficiaries with limited English proficiency should be able to self-identify and receive appropriate written and oral communication, and believe the regulation does allow this. First, anyone who self-identifies as having limited English proficiency would at that point be identified as such by the State as well as a result. Secondly, §438.10(c)(5) requires States and plans to notify potential enrollees and enrollees about the availability of oral interpretation, written information in prevalent languages, and how to access those services. Those services are available regardless of whether the State or plan identifies the beneficiary as having limited English proficiency, or the beneficiary self-identifies as such.

Comment: One commenter concurred with the requirement in §438.10(c)(3) on making translated material available, and limiting it to written information.

Response: We appreciate the commenter's support for this clarification.

Oral Interpretation (Proposed §438.10(c))

Comment: A few commenters noted that sign language was not specifically referenced in the proposed rule, and that interpretation for persons with hearing impairments is required by the Americans with Disabilities Act and title VI of the Civil Rights Act. One commenter suggested that clarification of this point in the regulation text would avoid confusion about the applicability of ADA requirements. The commenters recommended specifically including sign language and other interpreter services for beneficiaries with hearing impairments.

Response: We agree that sign language interpretation should be available for potential enrollees and enrollees with hearing impairments. However, §438.6(f) specifically requires MCOs, PIHPs, PAHPs, and PCCMs to comply with the Americans with Disabilities Act and other applicable Federal statutes. We do not believe it would be necessary or appropriate to restate all of the specific requirements of that law in this section of the regulation text.

Comment: A few commenters supported the availability of interpretation services, but believed it would be extremely difficult for most office-based physicians to set up and finance these services. They noted there is little coverage of these services by States, and the cost would be substantial for office-based physicians, often exceeding their reimbursement for the office visit itself. The commenters felt it was critical that we require States to create and fund systems to ensure appropriate interpretation services Statewide. They further stipulated that the services should be funded separately, not bundled into provider or capitation

payments.

Response: While we believe that it is appropriate and necessary to require that interpretation and translation services be available for all potential enrollees and enrollees, we also believe that the States should be afforded the flexibility to determine how these translation services are provided and paid for.

Comment: One commenter contended that the requirement in §438.10(c)(4) to make oral interpretation available for all non-English languages does not take into consideration special circumstances and characteristics of frontier States. To expect a State with a small population to have someone available to speak any possible language would be unreasonable in this commenter's view. This view was based on the commenter's belief that the increased cost and could result in decreased access if providers drop their participation in Medicaid. Another commenter argued that requiring oral interpretation for all languages was administratively burdensome and costly. The commenters recommended allowing State flexibility to determine if oral interpretation was necessary.

Response: We appreciate the difficulties in arranging for oral interpretation for languages that are less frequently encountered. However, we believe the proposed rule does not create any new requirements, but rather clarifies that existing requirements under title VI of the Civil Rights Act apply to Medicaid managed care programs. The OCR guidance reinforces this, but allows for flexibility in how oral interpretation is arranged. For example, it acknowledges that on-site interpretation may not always be realistic, in which case other options such as telephone language

lines may be used.

Comment: Numerous commenters supported the requirement for provision of oral interpretation. One commenter specifically supported the provision that it be available free of charge to each potential enrollee and enrollee, but believed the requirement should be strengthened. The commenter suggested adding language stipulating that oral interpretation is be provided when needed, and in a manner convenient to the beneficiary.

Response: We appreciate the commenters' support of this provision. We believe that some flexibility is appropriate, as noted in the OCR guidance, which sets forth a variety of factors to take into consideration when determining how to provide meaningful translation.

Alternative formats (Proposed §438.10(d)(2))

As noted above, proposed paragraph (d) specified the format for information, and that alternative formats must be available for those with special needs.

Comment: Numerous commenters supported the requirement that written material be available in alternative formats, but objected to the fact that the proposed rule did not expressly identify who was responsible for providing them. They believed that specifying responsibility was essential to ensuring that the information is transmitted in a timely manner. The commenters recommended that the final regulation specify that both the State and health plans have responsibility for making available their respective written materials in alternative formats.

Response: We believe that the proposed rule makes clear that written

material must be available in alternative formats. We believe that as drafted, it is clear that this requirement applies to whomever is providing the written material at issue to potential enrollees and enrollees. Therefore, we believe it is unnecessary to list each party in the regulations text.

Required information – general (Proposed §438.10 (e) through (g))

As noted above, proposed paragraph (e) described information requirements for potential enrollees; paragraph (f) set forth the general information requirements for enrollees of MCOs, PIHPs, PAHPs, and PCCMs, and paragraph (g) contained specific information requirements for MCO and PIHP enrollees.

Comment: One commenter noted that requiring specific information for potential enrollees and enrollees would require additional State and contractor financial and staff resources. The commenter believed this would lead to increased costs of production and distribution for both State and plans.

Response: We appreciate that additional resources may be needed to compile, produce, and disseminate the required information. However, we believe this information is critical for potential enrollees to make informed decisions, and enrollees to understand how to access services.

Information for Potential Enrollees (Proposed §438.10(e)(1)(i))

Comment: Numerous commenters believed the proposed rule would result in a delay in potential enrollees receiving information. The commenters noted that as proposed, the rule would require information be given to potential enrollees when they become eligible to voluntarily enroll in managed care, or face mandated

enrollment in managed care. They were concerned this could delay when beneficiaries receive the information, reducing the amount of time they have to digest it. Some commenters proposed that an additional option should be added, i.e., the time when the potential enrollee first becomes eligible for Medicaid. Others recommended adding the following language to §438.10(e)(1)(i): “when eligible to choose among MCOs, PIHPs, PAHPs, or PCCMs in a voluntary program.”

Response: We believe the proposed rule ensures that potential enrollees are provided required information at the earliest appropriate time. We acknowledge that a beneficiary may become Medicaid eligible first, and only later be eligible to enroll in a voluntary program, or required to enroll in a mandatory program. However, we are concerned that the provision of information for which the beneficiary has no immediate use will result in the information being disregarded. In the majority of cases, a beneficiary becomes a “potential enrollee” immediately upon Medicaid eligibility determination, and in these instances will get the information at the time suggested by commenters.

Comment: One commenter noted that the proposed rule does not expressly require the State to provide the required information on a plan to all potential enrollees in the plan’s service area. The commenter recommended adding this language.

Response: The proposed rule requires the State to provide the required information to all potential enrollees, which already would include all potential enrollees in a particular plan’s service area. Therefore, we believe it unnecessary to

add the recommended language on ensuring that the information must be provided to all potential enrollees in a plan's service area.

Summary Information for Potential Enrollees (Proposed §438.10(e)(2)(ii))

Comment: Some commenters supported proposed §438.10(e)(2)(ii), which provided that States need only provide summary information specific to each plan, with detailed information to be provided upon request. They believe this flexibility allowed States and plans to make better use of their resources by giving specific information only where it is needed to make informed choices, without broadly disseminating voluminous information that will generally receive little attention.

Another commenter was concerned that the requirement for States to provide only summary information – versus providing detailed information – would mean that many potential enrollees may not receive basic information on service areas, cost-sharing, benefits covered, provider information (including family planning), and other benefits not covered under contract. The commenter believed the burden in providing more detailed information is minimal, so the final rule should require the State to provide detailed information to all potential enrollees, not just upon request.

Numerous commenters specifically objected to proposed §438.10(e)(2)(ii)(E), which required the State to provide to potential enrollees only summary information on State plan services not covered by the contract. They believed this provision eliminated one way potential enrollees learn about the full range of what is available under the State plan. Some commenters were especially concerned that it was important for access to reproductive health services, which

plans may not offer. Some commenters were concerned that the delay caused by needing to ask for the information could result in a beneficiary being defaulted into such a plan. Finally, there were commenters who asserted summary information was not adequate to allow potential enrollees to make an informed decision.

Many of the commenters recommended that the final regulation require detailed – not summary – information on all items specific to each MCO, PIHP, and PAHP. Others also suggested the final rule require health plans to refer enrollees to a State sponsored, toll-free number that informs beneficiaries about how and where to access services plan the plan does not provide. They further suggested that this information be provided on an annual basis and at the point of service.

Response: We believe the proposed rule strikes the proper balance between providing needed information and ensuring the information is useful rather than overwhelming. The proposed rule does not preclude a State from providing detailed information. However, if it opts to provide summary information, then it must under §438.10(e)(12)(ii) ensure potential enrollees and enrollees are informed that more detailed information is available upon request, and how to request it.

Lists of Participating Providers (§438.10(e)(2)(ii)(D) and §438.10(f)(6)(i))

These proposed sections required the provision of a list of participating providers, including the name, phone number address, non-English languages spoken, and other information.

Comment: For potential enrollees, one commenter suggested limiting the list of providers on whom information is provided to hospital and primary care. The

commenter believed that providing a full specialty provider directory may create confusion on how to navigate the plan's referral process, giving the impression that referrals or authorization are not needed. The commenter recommended potential enrollees who want the specialty network information be directed to call the plan or enrollment broker.

Response: Although we acknowledge that including information on specialists adds to the volume of information and further complicates the process of keeping information current, we do believe that a significant number of potential enrollees rely on this information and therefore continue to believe that, at a minimum, information on provider networks should include information on primary care physicians, specialists, and hospitals.

Comment: One commenter believed that even in summary format, provider information would be too voluminous, and its value for potential enrollees is highly questionable. In the commenter's view, based on experience with managed care, people are more likely to read mailings that contain simple, limited information focusing only on the most important issues. The commenter suggested the requirement be limited to informing potential enrollees how they can obtain this information.

Another commenter was unclear how provider network information could be summarized. Even a summary could be voluminous, especially if it has to be kept up to date. The commenter asserted that States need flexibility to determine the most efficient method that will get accurate information to beneficiaries via the easiest

media. The commenter suggested making this information available upon request, with assistance available from both State and plans.

Response: For many potential enrollees, a decisive factor in selecting a plan is whether their current primary care provider is in the network. For beneficiaries with disabilities or chronic illnesses, participating specialists can carry the same weight. We believe the flexibility to summarize provider information will allow States to minimize the volume. For example, clinics or group practices could be identified in lieu of listing individual physicians. States and their contractors must highlight to potential enrollees how to obtain detailed listings or to inquire whether a specific provider is participating.

Comment: A commenter pointed out that identifying non-English languages spoken by providers – as required in §438.10(e)(2)(ii)(D) and §438.10(f)(6)(i) -- is an example of how the proposed rule would impose requirements on managed care programs which are not required in Medicaid FFS programs. In the commenter's view, it would be problematic to obtain this information, and the State could place itself at risk if it is construed that it is in some way "certifying" their ability to speak the language. Another commenter noted that maintaining information on non-English languages spoken by specialists and hospitals is extremely difficult due to the frequency with which it changes. The commenter recommended this only be required for PCPs.

Response: We acknowledge that this information may be problematic to obtain and keep current. However, it is our belief that potential enrollees and

enrollees need this information to make informed choices. We encourage States and plans to highlight to potential enrollees and enrollees that it is important to verify through a phone call or other means that the information is current.

Comment: A few commenters felt that it would be difficult to keep information on which providers are accepting new enrollees current – as required in §438.10(f)(6)(i) – especially in a printed format. One of the commenters suggested clarifying that plans may state in their materials that potential enrollees must contact the plan for oral updates of this information, or that they be required to keep the printed information reasonably up to date. Another commenter suggested that the final rule be revised to require the plan to prominently display a toll-free number to get this information. Another recommended the rule be clarified to provide that a plan’s best effort would be sufficient, or allow for a phone number to be available to provide the information.

Response: We acknowledge that this information is time sensitive; however, it is our belief that beneficiaries need this information to make an informed selection. Therefore, we encourage States and their contractors to highlight to potential enrollees and enrollees that it is important to verify through a phone call, or other means, that the information is still current. We also expect that States and their contractors will provide updates to provider directories within a reasonable time frame, although the exact time is left to the State to determine.

Required Information – General (Proposed §438.10(e) through (f))

Comment: One commenter observed that some of the information required

before and after enrollment is duplicative.

Response: We agree that the requirement to provide information on benefits, cost sharing, service area, and participating providers required for potential enrollees in §438.10(e)(2)(ii) duplicates required information for enrollees in §438.10(f)(6). However, we would note that for potential enrollees, States may provide summary information, with detailed information provided upon request. For enrollees, detailed information is necessary to understand the services for which they are covered and how to access them.

Comment: One commenter believes that all the required information for both potential enrollees and enrollees should be in writing, and should also be available to enrollees through a toll-free telephone number established by the State.

Response: While we expect that the required information will be provided in writing, we do not want to preclude other formats. We note that the "mechanism" for assisting enrollee understanding that we are requiring in response to comments on proposed §438.10(b) will provide another source of information, though as noted above, we believe States and plans are in the best position to determine the most effective mechanism to be used.

Comment: Numerous commenters believed that a core patient protection is access to information on the quality of health plan and providers. This conforms with the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. The commenters recommended requiring MCOs and PIHPs to provide to potential enrollees and enrollees, upon request, (1) information

on licensure, certification and accreditation status of MCOs and health care facilities; (2) information on education, licensure, Board certification and recertification; (3) a description of cost-control procedures; (4) summary descriptions of methods of compensation for physicians; and (5) information on the financial condition of the plan, including the most recent audit.

Response: We believe the provision in §438.10(g)(4), which requires MCOs and PIHPs to provide certain information upon request to enrollees, including information on the structure and operation of the plan, is sufficient to cover the bulk of the information the commenters specifically mentioned. As a result, we are not revising the regulations text to add additional references.

Notice of disenrollment (Proposed §438.10(f)(1))

Comment: One commenter suggested modifying the requirement for annual disenrollment notice to not apply when there is no lock-in, while several other commenters supported the requirement for States to notify enrollees of their disenrollment rights at least annually, and at least 60 days prior to each open enrollment period.

Response: We agree that the proposed rule as written would be awkward for a program with no lock-in provision. However, we believe it important for enrollees to be notified annually of their disenrollment rights under §438.56, even in a program with no lock-in, and therefore are not eliminating this provision.

Traditionally, States with no lock-in program could still delay the effective date of disenrollment to the beginning of the subsequent month, leading to a de facto

lock-in of 1 month. Section 1932(a)(4) of the Act did not eliminate this scenario, but did permit States to lock-in enrollees for up to a year. The Act also provides that if there is a lock-in, enrollees can disenroll without cause for the first 90 days of enrollment in an MCO, which assumes that a lock-in period will be at least 90 days long. Finally, the statute provides that if States have a lock-in, they must notify enrollees at least 60 days prior to each annual enrollment opportunity of the right to disenroll. We are revising the regulation to clarify that the 60-day timeframe for notifying enrollees of the right to disenroll applies solely to programs with lock-ins of 90 days or greater.

Annual notice (Proposed §438.10(f)(2) and §438.10(g))

Comment: Numerous commenters objected to the fact that the annual notice requirement in 438.10(f)(2) need only notify enrollees of the availability of required enrollee information (that is, that they may receive it upon request) rather than requiring that the information be furnished to all enrollees. Many commenters believed that the result would be that many enrollees would not receive information for many years, and would be unaware of their rights, because they did not bother to specifically ask for the information. Some commenters found this especially problematic in light of the fact that some services may not be provided because of the conscience clause. One commenter noted that an annual mailing of a full set of information typically is sent to enrollees in private health plans, and believed that Medicaid enrollees deserve no less. Another commenter argued that by actually furnishing all required information yearly, rather than only upon request, enrollees

are ensured timely information about their rights, as well as a complete compilation of the previous year's changes or amendments to services provided. Finally, a commenter expressed the view that the information in question is critical for enrollees deciding to remain with a particular plan or switch during an open enrollment season.

On a related issue, numerous commenters supported the MCO and PIHP-specific provisions in §438.10(g), but recommended the annual notice in §438.10(f)(2) be amended to require the information be provided in full on an annual basis.

Response: We appreciate the arguments for ensuring enrollees have up-to-date information on the managed care plans with which they are enrolled. However, we believe the proposed rule achieves a balance. The rule ensures enrollees receive detailed information upon enrollment. In §438.10(f)(4), we require plans to give each enrollee written notice of significant changes at least 30 days prior to the effective date of the change. To ensure that they are updated on all required information, we are adding a requirement at §438.10(f)(2) and (f)(3) that enrollees be updated on changes to required information in §438.10(g), regarding MCO- or PIHP-specific information.

Timing of information to enrollees (Proposed §438.10(f)(3) through (f)(5))

Comment: One commenter expressed concern about the requirement that plans send specified information to enrollees within a reasonable time after plans receive notice of enrollment. The commenter noted that in some cases, notice of

enrollment precedes the effective date by a wide enough margin that it will be confusing to send the information that early. The commenter suggested revising the language in the proposed rule to read “a reasonable time after the MCO received the notice of the recipient’s enrollment or the effective date of enrollment, whichever is later.”

Response: The regulation requires that the information be provided within a "reasonable time after it receives, from the State or the enrollment broker, notice of the recipient’s enrollment." We believe that the State is in the best position to define this specific time requirement (i.e., what is "reasonable") for providing this information.

Comment: One commenter noted that the requirement in §438.10(f)(4) for 30 days written notice of any significant change, as defined by the State, is not always possible to comply with, since States do not always have 30 days notice of such changes. However, numerous other commenters supported the provision to require plans to give 30 days prior notice of significant changes.

Response: While we understand that there may be instances in which plans receive less than 30 days notice of a change, we believe this would be the rare exception, and that a general rule for 30 days notice would generally be possible to meet. We believe that where it is possible, this timeframe should be satisfied, since we believe that it is needed in order to give enrollees adequate notice of significant changes that could affect their care. As a result, we are not changing this provision.

Comment: One commenter was concerned that the provision in

§438.10(f)(5) requiring 15 days notice to enrollees of their provider's termination from the plan's network was not enough to ensure continuity of care. The commenter recommended requiring 60 days notice, with prior approval by the State. The commenter further suggested that if 60 days notice is not given, the plan should pay for enrollee care from the terminating provider for 60 days or until the enrollee transfers to another plan.

Response: We recognize a more stringent threshold would likely further promote continuity of care, and we believe the proposed rule provides States with the discretion to do so. However, we also recognize the reality that providers often give little notice of their plans to terminate participation in a network. We believe the proposed rule provides a realistic threshold that protects enrollees' interests.

Required information for all enrollees (Proposed §438.10(f)(6))

Paragraph (f)(6) sets forth information that must be provided to all enrollees.

Comment: One commenter found that the requirement in §438.10(f)(6)(i), to provide the names and other information for hospital and specialists, would be impractical for a PCCM program, since all Medicaid-participating providers are eligible. The commenter observed that specialists also move, change offices, etc., making maintenance of such a list impractical. In addition, the commenter noted that identifying all participating PCCMs for enrollees does not seem necessary or reasonable.

Response: We agree with the commenter, and in response to this comment are conforming the language in §438.10(f)(6)(i) to the language in

§438.10(e)(2)(ii)(D), which clarifies that information on specialists and hospitals is only required for MCOs, PIHPs, and PAHPs. We are also clarifying the State need only identify participating PCCMs in an enrollee's service area.

Comment: Numerous commenters supported the statement in the preamble to the proposed rule that information provided must (1) clearly indicate which providers are available under any subnetworks with which a plan contracts, and (2) explain the procedures under which an enrollee may request a referral to an affiliated provider not in the subnetwork. These commenters believed that compliance with this requirement was especially important for women who may be obtaining services from a subnetwork that limits access to reproductive health services. The commenters recommended including an explicit requirement in the regulation text, specifically in §438.10(f)(6)(ii).

Response: While we do not believe it would be appropriate to dictate permissible contracting entities for plans, we do require under §438.10(e)(2)(iii) that if there are restrictions within a network, the beneficiary be informed of these restrictions as part of the information that they receive.

Comment: Numerous commenters noted that the preamble to the proposed rule specifically discussed the provision of information on pharmaceuticals, mental health and substance abuse benefits. H.R. 2564, as passed by the House, and supported by the President, specifically requires disclosure of prescription drug benefits. If the intent is for plans to disclose this information, the commenters believed that §438.10(f)(6)(v) should explicitly list them.

Response: We believe that the language in §438.10(f)(6)(v) already ensures full disclosure of information on all benefits, including prescription drug coverage and mental health benefits. It requires information on the “amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.” Since this applies to all contracted benefits, it is unnecessary to single out specific benefits in the regulation text.

Comment: Numerous commenters noted that proposed §438.62 would require States to ensure continued services to beneficiaries who are transitioning, out of an MCO, PIHP, PAHP, or PCCM, but did not require that enrollees be provided with information on how to obtain benefits during such a transition. The commenters recommended adding this as required information for enrollees.

Response: The proposed rule requires the State agency to actively arrange for continued services to beneficiaries transitioning in and out of a managed care system. We believe States should be given discretion as to how they fulfill that responsibility.

Comment: Several commenters supported the requirement in §438.10(f)(6)(vii) to specify the ability to access family planning providers out of network. They recommended clarifying that this requirements applies to all plans, not just those with conscience clauses.

Response: We believe that it is clear that the language in the proposed rule applies to all managed care programs (unless this obligation were ever waived under

a section 1115 demonstration), and are not making further revisions.

Comment: With respect to §438.10(f)(viii)(C), one commenter noted that in some frontier and rural States, 911 is not yet operational throughout the State. The commenter stated that printing and updating materials specific to the system in each locale would increase costs and burden. The commenter observed that this would also lead to another situation in which managed care requirements would be greater than those in fee-for-service.

Response: The requirement for providing information on how to use the 911 service is limited, implicitly, to areas where this service exists to use. For areas that have not yet implemented a 911 system, it would be acceptable for the State to generally instruct the enrollee to call their local emergency number without specifying the actual phone number. We believe that it is important, however, to include information on using 911 wherever this service is available.

Comment: One commenter asked why the requirements in §438.10(f)(6)(viii)(D) through (f)(6)(viii)(E) concerning the provision of information on emergency services applied to PCCM programs. The commenter believed that in PCCM programs, there were no additional restrictions on which emergency settings PCCM enrollees can use. The commenter believed there was no difference between PCCMs and regular FFS Medicaid on this point.

Response: While enrollees must be able to access emergency care at any hospital setting, MCOs, PIHPs, and PAHPs also often contract with specific hospitals for these services; in those instances, these contracted providers need to be

identified. We acknowledge that the only contracted providers in PCCM programs are PCPs. For PCCM programs, it will be sufficient for the State to direct enrollees to the nearest emergency room.

Comment: Numerous commenters supported the requirement in §438.10(f)(6)(viii) through (f)(6)(ix) that MCOs and PIHPs make certain information available to enrollees regarding how emergency services are covered, and the process for accessing these services. Some of the commenters, however, suggested that plans also be required to send required enrollee information on emergency care to affected providers and hospitals.

Response: Since an enrollee must be able to access emergency services at any hospital setting, it would be virtually impossible for plans to send the information to all such providers. For hospitals and providers with which plans contract to provide emergency services, §438.230(b)(2)(ii) requires that a subcontract “[s]pecifies the activities...delegated to the subcontractor,” so this would ensure that at least these providers would be aware of procedures regarding emergency services.

Comment: Numerous commenters believed there was a gap in proposed §438.10(f)(xii) with respect to how enrollees would be informed of where and how to obtain counseling or referral services that plans do not provide on the grounds of moral or religious objection. As written, these commenters asserted that the proposed rule does not require plans to provide information, nor refer enrollees to a source of information concerning these services. They acknowledged that States are

required to provide this information, but did not feel that it should be up to the enrollee to figure this out. Some commenters argued that requiring enrollees to go to two places to obtain information about how and where to access family planning services is confusing, constitutes a barrier to care, and could delay care unnecessarily. These commenters believed would this permit discrimination against women, ignoring their health care needs. Another commenter noted that remedying this problem would reduce State burden in complying with the requirements. A few commenters felt that as written, the proposed rule would permit plans to create “gag rules” against physicians and other health providers, who can be barred from even discussing how to find information about certain services. Finally, some commenters believed that this provision violated section 1932(b)(3)(B)(ii) of the Act, which requires plans to inform enrollees about services not covered because of moral or religious objections.

Several commenters recommended that plans be required to refer enrollees to where they can obtain the information addressed in section 438.10(f)(xii). Some commenters suggested that plans specifically provide referral to toll-free line – which States should be responsible for maintaining – that tells beneficiaries how and where to access services the health plan does not provide. A few also suggested that such a toll-free line be used to inform enrollees about the extent to which they can access out of network providers, including family planning (per §438.10(f)(6)(vii)), and services available under the State plan but not under the contract (per §438.10(f)(6)(xii)). Other commenters suggested that plans be required to inform

beneficiaries of all State plan services not available in the plan but otherwise available in Medicaid, and that this information be provided at point of service and annually.

Response: We believe it would be inappropriate, and inconsistent with the intent of the conscience clause provision, to require a health plan that morally objects to a service to provide information on how and where to access the service. This is why we provided in the regulations that the State should be responsible for doing so. We believe the proposed rule was clear, in stating that information must be "furnished" by the State, that the State had the responsibility of providing beneficiaries with this information, not merely making it available to them. It appears, however, that at least some commenters have inferred some lesser level of State responsibility from the fact that the word "furnish" was used instead of "provide," which is used elsewhere in the regulation text. While we believe these words to be interchangeable, the commenter seems to believe that furnish, as used here, means only that the materials must be furnished upon request (that is, "made available"). In order to avoid any such inferences, and to make it clear that States are required actually to provide this information to enrollees, we are revising the text of §438.10(e)(2)(ii)(E) and §438.10(f)(6)(xii) to use the word "provide" instead of "furnish" in describing the State's responsibility. We are also revising §438.102(d) to clarify the State is responsible for providing the required information not only for potential enrollees, but for enrollees as well. We believe States should be given discretion as to how they fulfill that responsibility.

MCO/PIHP specific information (Proposed §438.10(g))

Comment: One commenter urged that it be made clear how grievances and appeals work, not only within the health plans, but within State government as well.

Response: Section 438.10(g)(1)(i) requires that plans provide information on the State fair hearing process, as well as their own grievance procedures.

Comment: One commenter recommended that the required information for MCOs and PIHPs should also apply to PAHPs.

Response: The information requirements in §438.10(g) of the proposed rule reflect requirements elsewhere in the regulation that apply only to MCOs and PIHPs. However, in response to a comment on §438.2 and 438.8, two additional provisions on which information is required in §438.10(g) are being imposed on PAHPs. First, under § 438.8(b)(1)(ii), the advance directives requirement in §438.6(i)(2) now applies to the extent that the PAHP includes any of the providers listed in §489.102(a). Second, PAHP enrollees are entitled to an affirmation of their right to a State Fair Hearing. In response to this comment, and as noted above, we are adding a new paragraph (h) for PAHP-specific requirements (with proposed paragraph (h) renamed paragraph (i)), and including a reference to it in appropriate parts of §438.10(f). Finally, §438.6(h) and 438.8(b) of the proposed rule already extended the Physician Incentive Plan requirements of 434.70 to PAHPs. We are adding in the new paragraph (h) of §438.10, that this information be provided upon request.

Comment: One commenter was unclear as to why the information on provider appeal rights required by proposed §438.10(g)(1)(vii) was critical for

enrollees. In the commenter's view, enrollees already feel that the amount of information they currently receive is too much, or borders on it. The commenter suggested requiring plans to send notices of provider appeal rights to network providers rather than enrollees.

Response: The requirement in §438.10(g)(1)(vii) simply reflects the statutory requirement in section 1932(a)(5)(B)(iii) of the Act that information on "procedures available to . . . a health care provider to challenge or appeal the failure of the organization to cover a service." This should not be interpreted as creating a new right in Medicaid for providers to file an appeal. However, should the State, MCO, or PIHP provide for such a right, they must inform enrollees of its availability.

Comment: A few commenters noted that under the grievance and appeals rules in proposed subpart F of part 438, enrollees have the right to representation. These commenters were believed that grievances and appeals are complicated proceedings involving difficult to understand rules, and that enrollees should be made aware they have the option to obtain assistance. In addition, the commenters believed that enrollees should be protected against retaliation for filing an appeal or grievance, and provided with information on this right as well, so they will not forgo appeals out of fear of retaliation. The commenters recommended requiring health plans to inform enrollees they have a right to representation, and that they will not suffer from retaliation for filing an appeal or grievance.

Response: We agree that enrollees need to understand the grievance system for it to be effective. However, we note the proposed rule at §438.10(g)(1)(iv)

already stipulates that enrollees must be informed of the “availability of assistance in the filing process.” We believe this is sufficient to ensure enrollees understand the ability to obtain assistance, and are not adding the suggested clarification. We also disagree with the commenter that it is necessary to include an explicit statement that the beneficiary will not face retaliation for appealing. We do not believe that beneficiaries would assume that they would face retaliation in such a case.

Comment: A few commenters questioned the provision of complex information such the information on physician incentive plans provided under proposed §438.10(g)(3)(B). These commenters believed that many enrollees would not want such information, and may have difficulty understanding it, making its automatic provision counterproductive. The commenters recommended making it available upon request.

Response: We agree that requiring the provision of detailed information on physician incentive plans may be counterproductive. We are revising the regulation to provide at §438.10(g)(3)(B) to require MCOs and PIHPs to inform enrollees it is available upon request.

Comment: A few commenters objected to the lack of a requirement for plans to notify enrollees of their ability to obtain, upon request, information on requirements for accessing services, including factors such as physical accessibility. These commenters believed that if plans did not furnish this information, the enrollee would have to contact numerous providers to obtain such information. In an emergency, the commenters were concerned that this could delay lifesaving care.

One commenter referenced the need for TTY's service. Commenters also specifically noted that the 14th recommendation in CMS' Report to Congress on Special Needs addressed ensuring that plans and providers are physically accessible to those they will serve. Other commenters asserted that this was a requirement of the Americans with Disabilities Act. The commenters urged that plans be required to notify enrollees that this information is available upon request, and that this also be included in the annual notice.

Response: We believe that the overall requirements of this section, in particular the new requirement for a mechanism to assist beneficiaries understand the managed care program and their own plans requirements and benefits, will fulfill the needs identified by the commenters. Further, §438.6(f) specifically requires MCOs, PIHPs, PAHPs and PCCMs to comply with the provisions of the Americans with Disabilities Act and other anti-discrimination statutes. We do not believe any additional changes to the regulations text are necessary.

Comparative information under the State plan Option (Proposed §438.10(h)–current §438.10(i))

Comment: One commenter noted that there is a common understanding that quality and performance indicators are still evolving. This commenter believed that the reliability of such indicators for comparing plans varies for reasons such as difficulty in adjusting for factors not within the plan's control; reporting inconsistencies; or lack of statistical validity due to small plan size. The commenter recommended requiring States to address these issues as they determine which

measures to include, and how the information is presented, explained, and qualified. In addition, the commenter recommended that the final rule advise States whether there are circumstances in which reporting data that is not statistically valid would be misleading.

A few commenters urged that MCO information be consistent with HEDIS standards, and be based on the MCO's overall performance. Another commenter suggested giving States the latitude to develop and apply regional standards for comparative information. Finally, a commenter contended that disenrollment rates are not valid indicators when auto-assignment is used.

Response: We believe that States are aware of the evolving nature of quality indicators. The proposed rule includes the statutory discretion in section 1932(a)(5)(c)(iii) to provide quality indicators "to the extent available." We believe States are in the best position to determine which quality indicators to use, and that there is no impediment to regional standards for comparative information. With respect to disenrollment rates, we agree that there are valid concerns with respect to their use in a situation with auto-assignment. We note that disenrollment rates were not included in Medicaid HEDIS because of methodological problems, including the fact that most were related to loss of Medicaid eligibility. As a result, in response to this comment, we are revising the regulation at §438.10(i)(3)(iv) to delete the reference to disenrollment rates.

Comment: One commenter believed that the type, scope, nature, and format of the comparative information that must be furnished in the case of the State plan

option would be extremely costly. Another commenter argued that charting this information for individual PCCM providers would unduly complicate comparisons for enrollees, and be confusing for many service areas. This commenter believed that collection and maintenance would be cumbersome and costly to the State. The commenter suggested deleting this requirement for PCCMs.

Response: We recognize these requirements will result in some additional costs, but do not believe compliance will be as onerous as the commenter believes. The information on benefits, cost-sharing, and service area are already available to the State. We do not have any flexibility on the requirement that information be presented in a comparative chart-like format, since this is specifically required by section 1932(a)(5)(C) of the Act. We also do not have flexibility on the applicability of this requirement to PCCMs under section 1932(a)(1) authority, as this is also required under section 1932(A)(5). (Section 1932(a)(5) requires the provision of information on "managed care entities," which includes MCOs and PCCMs.)

There is flexibility for States to provide certain information that is identical across plans or PCCMs only once. For example, the State may provide a list of services provided or coordinated by all entities, and only identify and compare variations such as additional services provided, or services not provided because of the entity's religious or moral objections. The quality indicators are only required "to the extent available."

We are, however, clarifying that the State need only provide comparative information on MCOs and PCCMs on a service area basis, to ensure that enrollees

do not receive information on entities with which they cannot enroll.

Comment: One commenter believed that it did not make sense to require the comparative information to be provided to potential enrollees at least once a year. The commenter assumed this was an error. The commenter suggested making this information available to enrollees and potential enrollees, rather than furnishing it. The commenter further suggested that States be required to provide the information prior to enrollment or anytime upon request.

Response: The commenter is correct that we made an error. The error, however, was not the fact that the information be provided, rather than merely being made available upon request. Rather, the error was in omitting a reference to enrollees in what is now §438.10(i)(3). Section 1932(a)(5)(C) provides that “A State that requires individuals to enroll with managed care entities under paragraph (1)(A) shall annually (and upon request) provide, directly or through the managed care entity, to such individuals....” The statute thus requires that information be provided to all potential enrollees and enrollees, and contrary to the commenter’s suggestion that information only be made available upon request, it requires that this information be "provid[ed]" annually. Thus, in this respect, the regulation is not in error. We are making the needed correction to conform §438.10(i)(3) in this final rule with the statute. Specifically, we are clarifying that the information needs to be provided to potential enrollees in the timeframe required in §438.10(e)(1) (since enrollment is mandated for potential enrollees under section 1932(a)(1), these individuals would be enrollees when the obligation to provide information after one

year occurs), and that enrollees should receive it annually and upon request. Further, we are acknowledging in §438.10(i) that the comparative information required in this paragraph may duplicate what is required in §438.10(e) for potential enrollees and §438.10(f)(6) for enrollees.

Comment: A few commenters supported the idea that access to comparative information on health plans is essential to allow Medicaid beneficiaries to make informed choices. The commenters believed that exempting PIHPs and PAHPs from this requirement would undermine true competition among plans. The commenters recommended including PIHPs and PAHPs.

Response: The requirements in §438.10(i) (proposed §438.10(h) apply only to managed care programs operated under State plan amendment, as authorized by Section 1932(a)(1) of the BBA. States may only use this authority for mandatory MCO and PCCM programs; mandatory PIHP and PAHP programs cannot be operated under this authority. Thus, §438.10(i) applies, PIHPs and PAHPs that are not also PCCMs (if they were, they would be included as such) would not be among the plans from which beneficiaries could choose. As a result, we are not extending the requirement for comparative information to PIHPs and PAHPs as the commenter suggests.

Technical corrections

Comment: Some commenters noted areas where technical corrections are needed. In the introductory paragraph of §438.10(g), the reference should be to “438.10(f)” instead of “§438.10(e).” In §438.10(h)(1), they noted the correct

reference was “(h)(3),” not “(g)(3).” In §438.10(h)(3), they recommended changing “paragraph (d)” to “paragraph (e),” and changing “paragraph (g)(2)” to “paragraph (h)(2).”

Response: We appreciate the commenters pointing out the errors, and are making the recommended corrections. In addition, we are correcting a drafting error in §438.10(a), in the definition of “potential enrollee.” Specifically, we are deleting the words “in a” in the phrase “...not yet an enrollee of a specific in a MCO...”

6. Provider Discrimination (Proposed §438.12)

Proposed 438.12 would implement the prohibition on provider discrimination in section 1932(b)(7) of the Act. The intent of these requirements is to ensure that an MCO does not discriminate against providers, with respect to participation, reimbursement, or indemnification, solely on the basis of their licensure or certification. We extended this requirement to PIHPs and PAHPs in proposed §438.12. These requirements do not prohibit an MCO, PIHP or PAHP from including providers only to the extent necessary to meet their needs. Further, the requirements do not preclude an MCO, PIHP or PAHP from establishing different payment rates for different specialties, and do not preclude an MCO, PIHP or PAHP from establishing measures designed to maintain the quality of services and control costs, consistent with its responsibilities.

Comment: One commenter agreed that health plans should be prohibited from excluding providers from their networks for reasons that are inconsistent with public policy, such as discrimination against providers serving a high need

population or retaliation against providers who advocate on behalf of their patients. However, the commenter stated that the vast majority of health plans' decisions are wholly unrelated to these concerns. The commenter noted that the issuance of a written notice is unlikely to prevent the few cases of improper conduct. The commenter believed that the written notice provision would impose an unnecessary administrative burden and cost on health plans without substantially protecting providers, and therefore should be eliminated.

Response: We continue to believe that such notice is important to help enforce the anti-discrimination requirements in section 1932(b)(7) of the Act and §438.12. The notice will provide reasons why providers were not included in the MCO's, PIHP's, or PAHP's network and may be used by States in its monitoring efforts. Further, we estimate that it will take one hour to draft and furnish any given notice and on average each MCO, PIHP, and PAHP will only need to produce 10 notices per year.

Comment: One commenter strongly disagreed with this provision, as the commenter believed it was intervening with the ability of the MCO to contract and develop networks without undue restraint. The commenter specified that in a managed care business model, selection of networks is made on the basis of quality and market need and that States should be given the latitude to address these issues as part of their network analysis. The commenter also argued that this provision would handicap MCOs in requiring all providers be credentialed.

Response: We disagree with the commenter. Section 438.12, implementing

section 1932(b)(7) of the Act, provides sufficient latitude for MCOs, PIHPs and PAHPs with respect to network selection. This provision does not require MCOs, PIHPs and PAHPs to contract with providers beyond the number necessary to meet the needs of its enrollees. Further, this provision does not preclude these entities from establishing measures for provider selection that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees. Finally, this provision does not require entities to contract with any willing provider. We also would not have the discretion to eliminate this provision even if we agreed with the commenter, as it is set forth in the statute.

Comment: One commenter urged CMS to clarify in this section that Medicaid managed care entities may not prohibit or limit fully licensed physicians, such as psychiatrists from providing services within their scope of practice.

Response: The requirements in §438.12 are intended to ensure that an MCO, PIHP or PAHP does not discriminate against providers with respect to participation, reimbursement or indemnification solely on the basis of their licensure or certification. We do not believe it is appropriate to include the suggested statement, as this requirement does not pertain to scope of practice. Section 438.214 addresses provider selection and credentialing requirements.