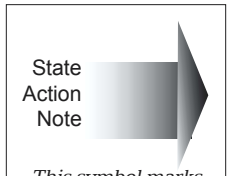
FIELD REPORT

September 2002

Medicaid Managed Care Final Regulations Issued

Overview

In June, the Bush Administration released final regulations implementing patient protections for Medicaid beneficiaries enrolled in managed care. These include protections such as requiring that beneficiaries have a choice of at least two plans and access to an adequate network of providers, establishment of an internal appeals process, and adoption of the "prudent layperson" standard for emergency care. The regulations provide regulatory guidance to states, managed care organizations, and beneficiaries on the important statutory changes made by the Balanced Budget Act (BBA) of 1997.[1] The regulations are important because 58 percent of Medicaid beneficiaries are enrolled in managed care.[2]



This symbol marks provisions where important details are left to the state.

The final rules leave states with considerable discretion to determine how to interpret a number of provisions. Beneficiaries and beneficiary advocates need to work with state governments to make sure the regulations are implemented in ways that ensure high-quality health care services. Advocates will also need to be aware of the protections afforded by the new rules. Finally, it is important to remember (as the preamble to the regulations points out) that these rules represent a *floor* or a minimum: States are permitted to enact more stringent consumer protections should they wish to do so.[3]

Why did it take so long? These regulations have been long delayed. Following a public comment period, the Clinton Administration issued final rules interpreting the BBA on January 19, 2001. The Bush Administration postponed the Clinton regulations three times before dropping them and issuing its own proposed rules for public comment on August 20, 2001. The protections in the June 2002 final rules are generally weaker than those in the Clinton Administration's rules but represent an improvement on the August 2001 version.

FamiliesUSA
The Voice for Health Care Consumers
and
HealthAssistance PARTNERSHIP
A Project of Families USA

1334 G Street, NW, 3rd Floor
Washington, DC 20005
202-628-3030 ■ Fax: 202-347-2417
www.familiesusa.org

When do the rules go into effect? States have until August 13, 2003 to bring all aspects of their managed care programs into compliance—including contracts, waivers, state plan amendments, and state operations. Some aspects of the regulations have already been implemented by the federal government through other, non-regulatory guidance.[4] However, as noted in the preamble to the regulations, states can apply for waivers from these new rules.

Where can I find the rules? The Federal Register citation for the rules is *Federal Register*, Friday, June 14, 2002, Vol. 67, No. 115, Part II, pages 40988-41116. The rules are available online at the Federal Register Web site (http://www.access.gpo.gov/su_docs/fedreg/a020614c.html). The rules are also available online at (http://www.cms.hhs.gov/medicaid/managedcare/).

Summary of the Main Provisions

§438 Subpart A – General Provisions

Subpart A covers definitions, contract requirements, types of plans affected, information requirements, and a prohibition on provider discrimination.

§438.8 Provisions that apply to PIHPs and PAHPs

One of the chief concerns of beneficiary advocates is that these regulations designate two new kinds of plans: prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). These prepaid health plans are subject to less regulation than managed care organizations (MCOs).

Definitions of PIHPs and PAHPs can be found in §438.2. In short, they differ from regular MCOs in that they do not have a comprehensive risk contract with the state but, rather, provide a subset of services such as dental care or behavioral health services. PAHPs are entities that do not provide any inpatient services. States have increasingly looked to prepaid health plans to provide a growing percentage of Medicaid managed care services.

§438.8 outlines the requirements that apply to PIHPs and PAHPs. The final version of these rules is somewhat better than the August 2001 proposed rules with respect to the consumer protections that would apply to beneficiaries receiving services through PIHPs and PAHPs. In general, people receiving services through PAHPs have fewer protections, but most of the protections that apply to other beneficiaries also apply to them. Exceptions are noted below.

§438.10 Information requirements

This section spells out the specific information that must be provided to two groups of people—enrollees and potential enrollees. Potential enrollees are Medicaid beneficiaries who are subject to mandatory enrollment or who may choose to enroll in managed care but are not yet enrolled with specific plans.

In general, states must provide information in a "manner and format that may be easily understood." States must also have a mechanism to help enrollees and potential enrollees understand the managed care program; states have discretion to determine what that mechanism will be. For a detailed list of what information must be provided to whom, see §438.10, paragraphs (e) and (f).

Information requirements for non-English speakers: The regulation requires states to develop a methodology for identifying non-English languages spoken by a significant number or percentage of enrollees and potential enrollees throughout the state (referred to as "prevalent" languages). Many states with large non-English-speaking populations have already developed rules governing non-English languages, but this may be an emerging issue for states with new, fast-growing immigrant populations. Once the "prevalent" languages have been identified, the state must provide all required information in each prevalent language.[5] In addition, the state must provide translation services and require all plans to do so for enrollees and potential enrollees—for *all non-English* languages, not just those that the state identifies as prevalent.

§438 Subpart B – State Plan Requirements

§438.50 State plan requirements

This section outlines who may and who may not be required to enroll in managed care and what requirements state plans must follow. The regulation also makes it clear that states may apply for Section 1115 or 1915(b) waivers to avoid complying with the requirements of this section.[6]

Public participation requirement: State plans must, among other things, specify the process that the state has used to involve the public in both the design and implementation of its managed care program. As most states have their programs already up and running, perhaps the most useful feature of this section is that the state must specify "the methods it uses to ensure ongoing public involvement once the State plan has been implemented."[7]

Limitations on enrollment: As the BBA made clear, Medicare dual-eligibles, children with special health care needs, and Indians (with some exceptions) cannot be required to enroll in managed care without a waiver. See §438.50 for more details.

Default enrollment: States must establish a default enrollment process for beneficiaries who do not choose a plan to enroll in (most states have already done this). Limited requirements for the default enrollment process are described in paragraph (f) of this section. The state must seek to preserve

"existing provider-recipient relationships"—defined as providers who have been the main source of Medicaid services for the beneficiary in the past year. The state must also seek to preserve relationships with providers that have traditionally served Medicaid beneficiaries (such as public hospitals, community health centers, etc.).

§438.52 Choice of plans and provider choice in rural areas

The state must offer beneficiaries—except those who live in rural areas—a choice of at least two plans. The preamble (p. 41020) again notes that states may apply for waivers from the choice-of-two-plans requirement. Residents of rural areas who are not offered a choice of plans must be able to choose from at least two physicians or case managers and be able to obtain services from other providers if appropriate providers are not available within their network. States may specify additional circumstances that determine out-of-network treatment for rural residents.

§438.56 Disenrollment

§438.56(b) describes the conditions under which plans may request disenrollment. Plans *may not* disenroll enrollees because their health status changes for the worse or because of their utilization of services, diminished mental capacity, or uncooperative behavior resulting from their special needs.

Enrollees may request to disenroll as follows:

- for cause, at any time ("cause" is defined as moving to another service area, needing services not available in-network, and other reasons, including poor quality of care, lack of access to covered services, lack of access to experienced providers, etc.);
- for the first 90 days following initial enrollment; and
- at least every 12 months thereafter.

The regulation describes the rules, including the time frame, for the handling of a disenrollment request.

§438 Subpart C – Enrollee Rights

§438.100 Enrollee rights

§438.100 establishes basic rights for all enrollees, including the right to:

- receive information in accordance with §438.10 (also see page 2);
- be treated with respect and with due consideration of their dignity and privacy;
- receive information on available treatment options and alternatives in a manner appropriate to their condition and ability to understand;

- participate in decisions regarding their health care, including the right to refuse treatment;
- be free from any form of restraint and seclusion used as a means of coercion, discipline, convenience, or retaliation; and
- request and receive a copy of their medical records and request that they be amended or corrected as specified in federal privacy rules.[8]

States must ensure that enrollees are free to exercise their rights. States must also ensure compliance with other federal/state laws, such as Title VI of the Civil Rights Act and the Americans with Disabilities Act.

§438.102 Provider-enrollee communications (the "gag rule")

This section establishes that plans may not prohibit or otherwise restrict health care professionals from advising or advocating on behalf of their patients. Known as the "gag rule," plans that violate these requirements are subject to intermediate sanctions described in Subpart I.

This section does include an exception for services that plans object to "on moral or religious grounds." Plans that do have such an objection are not required to inform enrollees about how and where to obtain the excepted services—but states are required to provide this information.

§438.104 Marketing activities

The BBA included a number of specific restrictions/protections on marketing activities that plans may engage in; the regulation implements those but leaves much else to state discretion.

The definition of marketing applies to materials and activities plans undertake that are directed at Medicaid beneficiaries who are not enrolled in that plan (in other words, the rules do not govern activities that a plan may undertake to retain its current members). Some of the key restrictions on marketing are as follows:

- states must approve marketing materials, and, in doing so, the state must *consult* with its Medical Care Advisory Committee;
- plans must distribute marketing materials to their entire service area as indicated in their contract;
- plans may not directly or indirectly engage in door-to-door, telephone, or other "cold call" marketing activities; and
- materials must be accurate and not misleading.

However, plans will still have plenty of opportunities to engage in marketing activities, if the state permits. For example a plan may market itself in public places such as eligibility offices if the state establishes rules under which plans may do so. This is an area that beneficiary advocates will have to monitor.

Limits on beneficiaries' financial obligations: §438.106 establishes that beneficiaries can't be held liable if a plan becomes insolvent. Beneficiaries also may not be "balance billed" should a provider regard a state's payments as inadequate. §438.108 applies existing Medicaid cost-sharing rules to any fees charged by managed care plans. Prior to the passage of the BBA, MCOs were not permitted to charge any cost-sharing. The BBA allowed MCOs to charge cost-sharing in accordance with existing Medicaid rules.

§438.114 Emergency and post-stabilization care

This section establishes the clear right of a Medicaid beneficiary to receive emergency room care at the nearest facility without prior authorization as long as the presenting condition meets the "prudent layperson" definition of an emergency. The "prudent layperson" definition is:

> *an emergency medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in . . . placing the health of the individual (or fetus) in serious jeopardy . . . Serious impairment to bodily functions . . . Serious dysfunction of any bodily organ or part.*

Subsections (b), (c), and (e) establish rules about payment for emergency and post-stabilization care. In general, plans (or the state, in the case of primary care case management entities [PCCMs]) must pay for treatment obtained under conditions that meet the prudent layperson definition. In the case of post-stabilization care, Medicare payment rules will apply.

§438 Subpart D – Quality Assessment and Performance Improvement

Subpart D discusses requirements for states and plans regarding quality of care and access to care.

§438.202 State responsibilities

For MCOs and PIHPs only, states must have a written strategy for assessing and improving the quality of services. States must obtain input on the proposed strategy from beneficiaries and other stakeholders, submit copies of the strategy to CMS, and periodically update the strategy.

Elements that must be included in the quality strategy are detailed in §438.204. For the most part, the regulations describe processes that states and plans must follow to assess quality. State responsibilities include setting most standards governing quality and access, defining populations with "special health care needs" and further scrutinizing their care, and determining what areas will be the focus of quality reviews. States must:

- assess the quality of care MCOs and PIHPs furnish to Medicaid beneficiaries overall;
- specifically examine the quality and appropriateness of care provided to individuals with special health care needs;
- identify the race, ethnicity, and primary language of Medicaid enrollees and give this information to the MCOs and PIHPs;
- regularly monitor MCO and PIHP compliance with standards regarding access to care, structure and operations, and quality measurement and improvement;
- use national performance measures and levels that CMS may require;
- provide for annual, external independent reviews of the quality, timeliness, and accessibility of services provided under MCO and PIHP contracts;
- have procedures for sanctioning MCOs that fail to comply with standards; and
- have an information system in place that allows them to review quality data.

§438.206 and §438.207 Access standards

All plans—MCOs, PIHPs, and PAHPs—must comply with access standards described in these sections. The federal rules provide very general access requirements, so states are left to set more specific standards. States are responsible for ensuring that all services covered by the Medicaid program are available and accessible to plan enrollees. ***Note to advocates:*** This requirement is stronger than the comparable fee-for-service requirement, which specifies that Medicaid services must be available to the same extent as services to the general population.

States must determine if a plan's provider network is adequate. They must assess networks when they first contract with plans and when there are significant changes, for example, in a plan's services, benefits, service area, or payments. States must consider the number, specialties, and experience of providers; the number of providers not accepting new Medicaid patients; providers' geographic locations; the availability of women's health providers for female enrollees; the availability of second opinions from qualified providers; and the characteristics, health needs, and service utilization of the people expected to enroll in the plan.

Plans must make services available 24 hours a day/7 days a week when "medically necessary" (see §438.210). States are responsible for setting further standards about timely access to care and incorporating these standards into managed care contracts. Plans must make sure their providers meet the state standards.

§438.208 Coordination and continuity of care

Generally, all health plans must deliver primary care and coordinate health care for enrollees. (States can make exceptions to this for some plans with a limited scope of service.)

For people with special health care needs, states and plans have additional responsibilities: Initially, states identify such enrollees to health plans. Then, MCOs, PIHPs, and PAHPs must use appropriate health care professionals to assess what special health conditions require treatment or monitoring. Enrollees who need a course of treatment or regular monitoring must be allowed direct access to an appropriate specialist.

States are responsible for defining people with special health care needs, and states *may* set standards and time frames for health plans' assessments of special health conditions. Because such definitions and standards would be "elements of state quality strategies" under 438.204, advocates and other stakeholders can have input into these state decisions. The preamble to the final rules discusses definitions and standards that various organizations have suggested nationally.

§438.210 Coverage and authorization of services

Through managed care contracts, states must specify the services health plans will offer and the amount, duration, and scope of those services. As in fee-for-service Medicaid, the services offered by plans must be sufficient in amount, duration, and scope to "reasonably be expected to achieve the purpose for which the services are furnished." Plans can take measures to control utilization, but they must still adhere to federal and state Medicaid laws and regulations regarding the provision of "medically necessary" care. States specify in their managed care contracts what constitutes medically necessary care, including the extent of services plans must cover related to "the prevention, diagnosis, and treatment of health impairments; the ability to attain age-appropriate growth and development; and the ability to attain, maintain, or regain functional capacity." If plans decide to deny authorization for a service, or authorize less service than was requested, the decision must be made by a health professional with appropriate expertise, and both the enrollee and the enrollee's provider must be given notice of the decision.

States can establish time frames for service authorizations. The standard time frame for authorizations cannot exceed 14 calendar days, and the expedited time frame for urgent health matters cannot exceed three working days (though this time limit can be extended in certain cases). Both standard and expedited authorizations are supposed to occur as expeditiously as the enrollee's health requires. Advocates are concerned that three working days may be too long a time frame for most expedited authorizations.

§438.214-§438.230 Structure and operations standards

The rules describe some structural requirements that apply to all types of plans (MCOs, PIHPs, and PAHPs). These sections include requirements about credentialing, recredentialing, and selection of providers; contractual requirements that plans have proper grievance, enrollment, and disenrollment systems and protect enrollees' confidentiality; requirements concerning enrollee information; and a requirement that plans monitor and hold subcontractors accountable for any delegated activities, revoking subcontracts if necessary for inadequate performance.

§438.236-§438.242 Measurement and improvement standards

The regulations do not specify what constitutes quality care. Rather, they require MCOs—and PIHPs and PAHPs when applicable—to adopt practice guidelines "based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field." Plans' coverage of services, utilization decisions, and enrollee education must be consistent with those guidelines.

MCOs and PIHPs (but not PAHPs) must conduct "performance improvement projects." This means that they must measure their performance in clinical and nonclinical areas; take steps to improve quality in those areas; re-evaluate their performance after the steps have been taken; and work to sustain or increase quality improvements. Areas for review may be specified by CMS and/or by the state. States must review plans' quality improvement projects as well as MCOs' and PIHPs' performance on any standard measures required by the state or CMS.

§438 Subpart F – Grievance System

§438.400 Definitions

A very important element of the final rules is the grievance system. Managed care organizations are required to have an internal appeals procedure. The state fair hearing is, in effect, the external appeal. The state may require that the enrollee exhaust the internal appeals process before the fair hearing process progresses. The fair hearing process still must adhere to existing Medicaid regulations.

An important change from the proposed rules is that the final rules allow enrollees to appeal the failure of a plan to provide services in a timely manner; plans that simply do not respond to requests for treatment, etc. may thus be held accountable. However, states are free to decide how to define "timely," so this will be an important issue for advocates to monitor.

Other causes for appeal include the following:

- the denial or limited authorization of a requested service;

- reduction, suspension, or termination of a service; and
- failure to allow use of out-of-network providers for rural beneficiaries.

Plans must set up grievance procedures (as distinct from an internal appeals process) so that beneficiaries have a process for registering complaints about all other issues, such as quality of care or personnel problems.

§438.402 General requirements

The enrollee or the provider, on behalf of the enrollee, may file (in writing or orally) a grievance, an appeal, or request for fair hearing. The filing must be completed between 20 and 90 days (at the state's discretion) from the date of the action (or inaction) being appealed.

§438.404 Notice of action

Plans must provide notice in writing that is easily understood (see page 2 on the information requirements in §438.10) and include the following:

- the action the plan has taken or plans to take,
- how to appeal,
- how to get an expedited review, and
- how to request continuation of benefits that are being discontinued.

Time frames for this notice are specified.

§438.406 Handling of grievances and appeals

The plan must do the following:

- give reasonable assistance to the enrollee, including interpreter services;
- assure that the reviewers were not involved in previous decision-making on the case and have "appropriate clinical expertise" (as defined by the state);
- provide the enrollee with a reasonable opportunity to present evidence and allegations of fact or law, in person and in writing; and
- provide the enrollee or representative opportunity to examine the case file.

§438.408 Resolution and notification

The plan must resolve each appeal or grievance and give notice as expeditiously as the enrollee's health requires, within state-established time frames. The rule specifies the longest acceptable time frame; states may choose to shorten these time frames.

- Grievance: 90 days
- Appeal: 45 days

- Expedited appeal: 3 working days. An expedited appeal is one in which the plan or a provider supporting the enrollee's request determines that a regular appeal would "seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function."[9]

Plans may extend these time frames under certain circumstances.

§438.420 Continuation of benefits

This section details the specific guidelines under which an enrollee may continue to receive a disputed service while the appeal and fair hearing are pending. The plan may recover the cost of the service if its decision to deny the service is upheld.

§ 438.424 Implementing reversed appeal resolutions

If the enrollee's claim is upheld, the plan must furnish the service as expeditiously as possible.

Conclusion

Beneficiaries have waited many years for the protections embodied in the final regulations. While these protections could be stronger, it is important that beneficiaries and their advocates be aware of them and take advantage of them. In addition, as states implement these regulations, beneficiary advocates should plan to play a role in the process, particularly in the areas of state discretion identified above. The best opportunity to do so will be when states renegotiate their contracts with health plans.

Additional Resources

National Health Law Project (www.healthlaw.org)

Center for Health Services Research and Policy, George Washington University (www.gwhealthpolicy.org)

Families USA (www.familiesusa.org)

---

[1] The Balanced Budget Act of 1997 allowed states the flexibility to require Medicaid beneficiaries to enroll in managed care. In exchange, Congress enacted some important patient protections. For more on the BBA, see Families USA, *Balanced Budget Bill Enacted, Field Report* (Washington: Families USA, August 1997) and Families USA, *Medicaid Managed Care Consumer Protection Regulations: No Patients' Rights for the Poor?* Special Report (Washington: Families USA, May 2001).

[2] HHS Press Release, "HHS Issues New Medicaid Managed Care Regulation to Guarantee Strong Patient Protections," June 13, 2002.

[3] See p. 41024 of the *Federal Register*, June 14, 2002. All further page references are to this edition of the *Federal Register*.

[4] See p. 40990 for a list of State Medicaid Director letters on managed care provisions of the BBA.

[5] See §438.10(c).

[6] See §438.50(a).

[7] See §438.50(b)(4).

[8] Other privacy protections may apply as well. For an analysis of federal privacy rules, see (www.healthprivacy.org/newsletter-url2305/newsletter-url_list.htm?section=Regulations).

[9] §438.410(a). See §438.410 for more details on expedited appeals.

This report was written by:

Joan Alker

Cheryl Fish-Parcham

Judy Waxman

The following Families USA staff contributed to the preparation of this report:

Peggy Denker

Nancy Magill

Ingrid VanTuinen