

enrollee's request for an expedited review.

Comment: One commenter asked who will determine which route is more appropriate for the beneficiary in pursuing a remedy to a complaint, since we acknowledge that the same claim or circumstances that gave rise to an appeal could have elements of a grievance. This may cause the beneficiary to be confused as to which route is more appropriate. Another commenter asserted that M+C organizations should be required to provide clear, accurate and standardized information concerning grievance and appeal procedures.

Response: We are adding to § 422.564(b) a requirement that when an M+C organization receives a complaint, it must promptly determine and inform the enrollee whether the issue is subject to its grievance procedures or its appeal procedures. Note that we view "complaint" and "dispute" as generic terms that cover various expressions of dissatisfaction or disagreement that may be brought to the attention of an M+C organization or its providers. Thus, complaints or disputes can encompass grievable or appealable issues, but in either case would require resolution in accordance with the organization's internal procedures.

CMS already requires M+C organizations to provide clear and concise information to all enrollees regarding appeal and grievance procedures. M+C organizations include this information annually in their Evidence of Coverage (EOC). In addition to other information that M+C organizations wish to convey, CMS also provides standard information that all EOCs must contain regarding appeals and grievances.

Comment: Various commenters expressed conflicting views on the most appropriate means for dealing with quality of care issues. Some commenters believed that a quality of care issue should first be resolved by the M+C organization and subsequently sent to the QIO. Other commenters argued that quality of care issues should be referred immediately to the QIO for resolution, while others maintained that complaints should be processed by both M+C organizations and QIOs simultaneously.

Response: As reflected under new § 422.564(c), we decided that the most flexible approach would be to permit enrollees to file quality of care complaints with either the M+C organization, the QIO, or both. We expect M+C organizations and QIOs to coordinate and cooperate with one another to resolve enrollees' complaints.

Comment: Many commenters suggested that CMS should not include a definition of "quality of care" in the regulations because defining it would oversimplify the many issues that quality of care might encompass.

Response: We agree with the commenters that the term "quality of care" does not lend itself to a regulatory definition. Instead, we will rely on the States and M+C organizations to identify the types of issues that might fall into the quality of care category.

Comment: A commenter questioned how CMS would enforce record-keeping requirements for M+C organization grievances.

Response: Section 422.564(e) requires M+C organizations to maintain records associated with processing grievances. M+C organizations already should have a system to track and maintain records on all grievances in light of existing requirements under section 1852(c)(2)(C) and § 422.111(c)(3), whereby M+C organizations must report aggregate information on the disposition of grievances. Thus, the record-keeping requirement will be enforced through CMS' existing procedures to monitor grievance activities, and if appropriate, place M+C organizations on corrective action plans. We expect M+C organizations, at a minimum, to keep track of the receipt date and final disposition of the grievance, and the date that the M+C organization notified the enrollee of the disposition.

E. Reductions of Services

This final rule does not set forth any new regulations regarding reductions in services. As part of the *Grijalva* settlement, we agreed to solicit comments on whether new notice and appeal procedures were needed for decisions by M+C organizations to reduce health services. The issue of what constitutes appropriate notice and appeal procedures for reductions of service was also raised in the regulations to implement the M+C program.

In the M+C final rule, we made several changes to § 422.566(b), which describes actions that constitute organization determinations. We added language at § 422.566(b)(3) to clarify that an organization's refusal to pay for or provide services, in whole or in part, "including the type or level of services" can constitute an organization determination if the enrollee believes that services should be furnished or arranged. We stated in the preamble to the final rule that we agreed that a reduction in service could be considered an organization determination that was subject to an

appeal. To the extent that the organization refused to continue to provide all or part of the services that the enrollee believed should be furnished, the reduction constituted an appealable issue.

However, the existing M+C regulations do not specify that notices are routinely required in connection with reductions of services. The notices are required only if the enrollee disagrees that the services are no longer medically necessary.

We have reviewed several public comments on these issues, both after the publication of the M+C interim final rule on June 26, 1998, and again with respect to the January 24, 2000, proposed rule. Several commenters both times strongly urged us to consider the administrative and financial burden associated with notice requirements. They maintained that it is unnecessary to require notification to enrollees when services are reduced because the normal progression of a clinical course of treatment is from increased to decreased services. Some commenters have argued that providing detailed notices in all reduction situations would be confusing, burdensome and intrusive upon the physician/patient relationship.

Based on our review of current and previous comments on this issue, we believe that the process of changing the notice requirement for reductions of services is unnecessary, particularly in light of the requirement that all enrollees receive notice of their appeal rights before the termination of services in hospital and other provider settings. We will monitor the new policy on discontinuations of provider services, and if we find that it is necessary to create additional procedures for reductions of services, we will initiate the necessary rulemaking.

IV. Provisions of This Final Rule With Comment Period

A. Summary of Provisions

For the convenience of the reader, listed below are the major changes to the M+C regulations that are set forth in this final rule with comment period. This listing is intended solely as a reference aid rather than as a comprehensive statement of the policies set forth in the regulation text.

- New § 422.502(i)(3)(iv) specifies that M+C organization contracts with providers and other related entities entered into after (the effective date of this final rule) must contain a provision specifying that these entities will comply with the applicable notice and appeal provisions in §§ 422.620, 422.624, and 422.626.