

organization determination under § 422.566(c). One commenter supported the elimination of the cross-reference with the provision that only treating or attending providers involved with the enrollee's health care should be allowed to request organization determinations.

Another commenter believed that in an effort to discourage inappropriate use of the process, providers should only be allowed to make requests for organization determinations with the full knowledge and agreement of the enrollee. The commenter recommended that we establish this distinction in the preamble or regulation, and, if an enrollee indicates that a requested organization determination is inconsistent with his or her wishes, then the M+C organization should be able to cease action on the request.

*Response:* We believe that the text, "any provider that furnishes, or intends to furnish, services to the enrollee," already addresses the commenter's concern that the provider requesting an organization determination be involved with the enrollee's health care. Because enrollees in some M+C plans are free to seek care from providers within or outside of the M+C organization's network and all enrollees may go out of network for emergency and certain other services, we believe it is appropriate to use the all-inclusive term "any," instead of "treating," to describe the providers furnishing, or intending to furnish, services to enrollees.

We agree with the second commenter that providers should request organization determinations only with the full knowledge and agreement of enrollees. This is particularly important for unaffiliated providers that might seek payment for services already furnished to enrollees. In addition, an M+C organization may cease action on a provider's request for an organization determination that is inconsistent with an enrollee's wishes.

## 2. Effectuation Times When M+C Organizations File Appeals

The current regulations at § 422.618 and § 422.619 establish effectuation times when an M+C organization's denial of coverage or payment is overturned, either through its own reconsideration process or by an independent outside entity. Effectuate means to authorize, pay for, or provide coverage. The M+C organization may not appeal the independent outside entity's decision. Section 422.618 also requires that, if the independent outside entity's determination is reversed (in whole or in part) by an administrative law judge (ALJ), or at a higher level of appeal, the M+C organization must pay

for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date the M+C organization receives notice reversing the determination. In these situations, the M+C organization, like an enrollee, has 60 days to appeal.

The ambiguity in the current regulations, which require effectuation of a determination within 60 days, but also permit further appeal within the same time frame, results in confusion. To reconcile these two regulatory provisions, we proposed to revise the rules so that M+C organizations may await the outcome of a Departmental Appeals Board (the Board) review before effectuating a decision of an ALJ. This change would serve to balance the M+C organization's right to appeal with the need to ensure that an enrollee would not be faced with a potentially large debt in the event that the Board overturns the ALJ after the service has been furnished to the enrollee.

In § 422.618(c), we proposed to retain, as the general rule, the 60-day effectuation requirement for reversals by an ALJ or higher level of appeal. This is because we did not want to effectively negate the M+C organization's 60-day right to request an appeal to the Board or higher level. However, our expectation was that M+C organizations would not take the maximum 60 days to effectuate a decision they do not intend to appeal. We proposed to redesignate the current § 422.618(c), as § 422.618(c)(1) and provide that the 60-day deadline for effectuation was the "general rule." We then proposed to add a new § 422.618(c)(2) which would allow for an exception to the 60-day standard if the M+C organization decided to request a Board review consistent with § 422.608. We proposed to allow the M+C organization to await the outcome of the Board review before it pays for, authorizes, or provides the service under dispute. Under the provision, we would require an M+C organization that files an appeal with the Board concurrently to send a copy of its request and any accompanying documents to the enrollee. Additionally, in the proposed rule, the M+C organization was required to notify the independent review entity of the requested appeal.

Consistent with this change, we also proposed to revise § 422.619(c) with regard to effectuating expedited reconsidered determinations. As in standard appeals, we proposed to allow an exception for the M+C organization to await the outcome of the Board's review before the M+C organization authorizes or provides the service under

dispute. Additionally, an M+C organization that files an appeal with the Board would be required concurrently to send a copy of its request and any accompanying documents to the enrollee, as well as notifying the independent review entity of the requested appeal.

*Comment:* Some commenters believe that the 60-day time frame for an M+C organization to decide whether to appeal (and ultimately pay for or provide a service) is too long. One commenter suggested that the time frame to allow an M+C organization to appeal to the Departmental Appeals Board (DAB) should be reduced to 30 days. Another commenter believes that M+C organizations generally know well before 60 days whether they intend to appeal an administrative law judge's (ALJ's) decision. Instead, an M+C organization more likely would need a 60-day time frame to gather evidence in support of an appeal. The commenter argued that, since enrollees already wait a long time for ALJ decisions, enrollees should not be made to wait another 60 days to receive care.

Other commenters supported our attempt to reconcile the provisions that, on the one hand, allow an M+C organization the right to appeal an ALJ's decision, but, on the other hand, require the M+C organization to effectuate the decision before a final DAB decision. One commenter supported a 60-day, rather than a 72-hour, effectuation time frame for expedited reviews.

*Response:* Currently, § 422.618(c)(1) and § 422.619(c)(1) require an M+C organization to pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date that the M+C organization receives a decision reversing a determination. Section 422.608 also provides for an appeal by the M+C organization within the same 60-day time period that effectuation must occur. While we appreciate the commenters' concerns that 60 days seems like a long time for M+C organizations to appeal, we believe that we should allow M+C organizations the same 60-day time frame afforded to other parties when they file appeals. Thus, we will maintain the current 60-day standard at § 422.608 for all parties seeking review by the DAB.

We recognize that an enrollee may encounter a delay in obtaining a service if an M+C organization appeals; however, both the DAB and the ALJ hearing offices have procedures to screen cases and to give priority to pre-service denial cases, including immediate assignment and resolution of