

written confirmation to the enrollee within 3 calendar days.

(4) *How the M+C organization must request information from noncontract providers.* If the M+C organization must receive medical information from noncontract providers, the M+C organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the M+C organization affirms, in whole or in part, its adverse expedited organization determination, the M+C organization must submit a written explanation and the case file to the independent entity contracted by HCFA as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(e) *Notification of enrollee.* If the M+C organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

(f) *Failure to meet timeframe for expedited reconsideration.* If the M+C organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the M+C organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

(g) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in mak-

ing the organization determination must conduct the reconsideration.

(2) When the issue is the M+C organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000]

**§ 422.592 Reconsideration by an independent entity.**

(a) When the M+C organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with HCFA.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same parties listed in § 422.582(d) who qualified during the M+C organization's reconsideration, with the addition of the M+C organization.

**§ 422.594 Notice of reconsidered determination by the independent entity.**

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to HCFA.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions in understandable language;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the M+C organization's adverse organization determination), inform the parties of their right to an ALJ

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hearing if the amount in controversy is \$100 or more;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by HCFA.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000]

**§ 422.596 Effect of a reconsidered determination.**

A reconsidered determination is final and binding on all parties unless a party other than the M+C organization files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

[65 FR 40331, June 29, 2000]

**§ 422.600 Right to a hearing.**

(a) If the amount remaining in controversy is \$100 or more, any party to the reconsideration (except the M+C organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ. The M+C organization does not have the right to request a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with § 405.740 of this chapter for Part A services and § 405.817 of this chapter for Part B services.

(c) If the basis for the appeal is the M+C organization's refusal to provide services, HCFA uses the projected value of those services to compute the amount remaining in controversy.

**§ 422.602 Request for an ALJ hearing.**

(a) *How and where to file a request.* A party must file a written request for a hearing at one of the places listed in § 422.582(a) or with the independent, outside entity. The organizations listed in § 422.582(a) forward the request to the independent, outside entity, which is responsible for transferring the case to the appropriate ALJ hearing office.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in 20 CFR 404.933(c), a party must file a request for a hearing within 60

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days of the date of the notice of a reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the M+C organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *When the amount in controversy is less than \$100.* (1) If a request for a hearing clearly shows that the amount in controversy is less than \$100, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than \$100, he or she discontinues the hearing and does not rule on the substantive issues raised in the appeal.

**§ 422.608 Departmental Appeals Board (the Board) review.**

Any party to the hearing, including the M+C organization, who is dissatisfied with the ALJ hearing decision, may request that the Board review the ALJ's decision or dismissal. Regulations located at 20 CFR 404.967 through 404.984 regarding SSA Appeals Council Review apply to Board review for matters addressed by this subpart.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998]

**§ 422.612 Judicial review.**

(a) *Review of ALJ's decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of an ALJ's decision if—

(1) The Board denied the party's request for review; and

(2) The amount in controversy is \$1,000 or more.

(b) *Review of Board decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of the Board decision if it is the final decision of HCFA and the amount in controversy is \$ 1,000 or more.

(c) *How to request judicial review.* A party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of