for, or reimbursed by the MA organization.

(3) The MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.

(4) Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment.

(5) Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

(c) *Who can request an organization determination.* (1) Those individuals or entities who can request an organization determination are—

(i) The enrollee (including his or her representative);

(ii) Any provider that furnishes, or intends to furnish, services to the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) Those who can request an expedited determination are—

(i) The enrollee (including his or her representative); or

(ii) A physician (regardless of whether the physician is affiliated with the MA organization).

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 68 FR 50858, Aug. 22, 2003; 70 FR 4739, Jan. 28, 2005; 75 FR 19812, Apr. 15, 2010; 75 FR 32859, June 10, 2010; 76 FR 21569, Apr. 15, 2011; 84 FR 15834, April 16, 2019; 88 FR 22334, Apr. 12, 2023]

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard organization determination by making a request with the MA organization or, if applicable, to the entity responsible for making the determination (as directed by the MA organization), in accordance with the following:

(1) The request may be made orally or in writing, except as provided in paragraph (a)(2) of this section.

(2) Requests for payment must be made in writing (unless the MA organization or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(b) *Timeframes*—(1) *Requests for service or item.* Except as provided in paragraph (b)(1)(i) of this section, when a party has made a request for a service or an item, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

(i) *Extensions; requests for service or item.* The MA organization may extend the timeframe by up to 14 calendar days if—

(A) The enrollee requests the extension;

(B) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(C) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(ii) *Notice of extension.* When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) *Requests for a Part B drug.* An MA organization must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. This 72-hour period may not be extended under the provisions in paragraph (b)(1)(i) of this section.

(c) *Timeframe for requests for payment.* The MA organization must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee a written notice if—

(1) An MA organization decides to deny a service or an item, Part B drug, or payment in whole or in part, or reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment.

(2) An enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item, service or Part B drug, in whole or in part.

(e) *Form and content of the MA organization notice.* The notice of any denial under paragraph (d) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service, item, and Part B drug denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by CMS.

(f) *Effect of failure to provide timely notice.* If the MA organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

(g) *Dismissing a request.* The MA organization dismisses an organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an organization determination under § 422.566(c).

(2) The MA organization determines the party failed to make out a valid request for an organization determination that substantially complies with paragraph (a) of this section.

(3) An enrollee or the enrollee's representative files a request for an organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the organization determination.

(4) A party filing the organization determination request submits a timely request for withdrawal of their request for an organization determination with the MA organization.

(h) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(i) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for an organization determination within 6 months from the date of the notice of dismissal.

(j) *Effect of dismissal.* The dismissal of a request for an organization determination is binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under paragraph (i) of this section.

(k) *Withdrawing a request.* A party that requests an organization determination may withdraw its request at any time before the decision is issued by filing a request with the MA organization.

[65 FR 40329, June 29, 2000, as amended at 70 FR 4739, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 75 FR 19812, Apr. 15, 2010; 75 FR 32859, June 10, 2010; 80 FR 7961, Feb. 12, 2015; 84 FR 23880, May 23, 2019; 86 FR 6101, Jan. 19, 2021]

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the MA organization) may request that an MA organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the determination, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The MA organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the MA organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 72-hour or 14-day timeframe, as applicable, established in § 422.568 for a standard determination. The timeframe begins when the MA organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an MA organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.