

(1) Within 12 months from the date of the notice of the initial or reconsidered determination to the party to such determination;

(2) After such 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.988(b) and 404.989); or

(3) At any time, when:

(i) Such initial, revised, or reconsidered determination or such decision or revised decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting clerical error or error on the face of the evidence on which such determination or decision was based; or

(ii) Such initial, revised, or reconsidered determination or such decision or revised decision was procured by fraud or similar fault of the beneficiary or some other person.

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996; 62 FR 25853, 25855, May 12, 1997]

§ 405.753 Appeal of a categorization of a device.

(a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart H—Appeals Under the Medicare Part B Program

AUTHORITY: Secs. 1102, 1842(b)(3)(C), 1869(b), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b), and 1395hh).

SOURCE: 32 FR 18028, Dec. 16, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.801 Part B appeals—general description.

(a) The Medicare carrier makes an initial determination when a request for payment for Part B benefits is submitted. If an individual beneficiary is dissatisfied with the initial determination, he or she may request, and the carrier will perform, a review of the claim. Following the carrier's review determination, the beneficiary may obtain a carrier hearing if the amount remaining in controversy is at least \$100. The beneficiary is also entitled to a carrier hearing without the benefit of a review determination when the initial request for payment is not being acted upon with reasonable promptness (as defined in § 405.802). Following the carrier hearing, the beneficiary may obtain a hearing before an ALJ if the amount remaining in controversy is at least \$500. If the beneficiary is dissatisfied with the decision of the ALJ, he or she may request the Departmental Appeals Board (DAB) to review the case. Following the action of the DAB, the beneficiary may file suit in Federal district court if the amount remaining in controversy is at least \$1,000.

(b) The rights of a beneficiary under paragraph (a) of this section to appeal the carrier's initial determination are granted also to—

(1) A physician or supplier that furnishes services to a beneficiary and that accepts an assignment from the beneficiary, or

(2) A physician who meets the conditions of section 1842(l)(1)(A) of the Act pertaining to refund requirements for nonparticipating physicians who have not taken assignment on the claim(s) at issue.