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, CMS'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]

Subparts I–Q [Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1801 Introduction.

(a) *Definitions.* As used in this subpart:

Administrator means the Administrator or Deputy Administrator of CMS.

Administrator's review means that review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and § 405.1875.

Board means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 1395oo) and § 405.1845.

Board hearing means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 1395oo(a)), and § 405.1835.

Date of filing and *date of submission of materials* mean the day of the mailing (as evidenced by the postmark) or hand-delivery of materials, unless otherwise defined in this subpart.

Date of receipt means the date on the return receipt of "return receipt requested" mail, unless otherwise defined in this subpart.

Intermediary determination means the following:

(1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24(f) of this chapter, the term means a determination of the amount of total reimbursement due the provider, pursuant to § 405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a determination of the total amount of payment due the hospital, pursuant to § 405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases "intermediary's final determination" and "final determination of the Secretary", as those phrases are used in section 1878(a) of the Act.

(4) For purposes of § 405.376 concerning claims collection activities, the term does not include an action by CMS with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

Intermediary hearing means that hearing provided for in § 405.1809.

(b) *General rule*—(1) *Providers.* The principles of reimbursement for determining reasonable cost and prospective payment are contained in parts 413 and 412, respectively, of this chapter. In order to be reimbursed for covered services furnished to Medicare beneficiaries, providers of services are obliged to file cost reports with their intermediaries as specified in § 413.24(f) of this chapter. Where the term "provider" appears in this subpart, it includes hospitals paid under the prospective payment system for purposes of applying the appeal procedures described in this subpart to those hospitals.

(2) *Other entities participating in Medicare Part A.* In addition to providers of services whose status as such is indicated in the Act, there are entities