

(2) A sponsor may request review by CMS only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor CMS's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both CMS and the sponsor of its decision.

(c) *Request to CMS.* If the FDA does not agree to recategorize the device, the sponsor may seek review from CMS. A device sponsor must submit its request in writing to CMS. CMS obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. CMS reviews all material submitted by the sponsor and the FDA's recommendation. CMS reviews only information in the FDA record to determine whether to change the categorization of the device. CMS issues a written decision and notifies the sponsor of the IDE and the FDA.

§ 405.215 Confidential commercial and trade secret information.

To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u,

1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

GENERAL PROVISIONS

§ 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or

(2) The provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the third year following the year in

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which notice was sent to such individual that such amount had been paid.

[41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 49271, Sept. 19, 1996]

§ 405.351 Incorrect payments for which the individual is not liable.

Where an incorrect payment has been made to a provider of services or other person, the individual is liable only to the extent that he has benefited from such payment.

§ 405.352 Adjustment of title XVIII incorrect payments.

Where an individual is liable for an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) adjustment is made (to the extent of such liability) by:

(a) Decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937, to which the individual is entitled; or

(b) In the event of the individual's death before adjustment is completed, by decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937 payable to the estate of the individual or to any other person, that are based on the individual's earnings record (or compensation).

[31 FR 13534, Oct. 20, 1966, as amended by 41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.

As soon as practicable after any adjustment is determined to be necessary, the Secretary, for purposes of this subpart, shall certify the amount of the overpayment or payment (see § 405.350) with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1937, such certification shall be made to the Railroad Retirement Board.

§ 405.354 Procedures for adjustment or recovery—title II beneficiary.

The procedures applied in making an adjustment or recovery in the case of a

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title II beneficiary are the applicable procedures of 20 CFR 404.502.

[31 FR 13534, Oct. 20, 1966, as amended at 32 FR 18027, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.355 Waiver of adjustment or recovery.

(a) The provisions of § 405.352 may not be applied and there may be no adjustment or recovery of an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) in any case where such incorrect payment has been made with respect to an individual who is without fault, or where such adjustment or recovery would be made by decreasing payments to which another person who is without fault is entitled as provided in section 1870(b) of the Act where such adjustment or recovery would defeat the purpose of title II or title XVIII of the Act or would be against equity and good conscience. (See 20 CFR 404.509 and 404.512.)

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault shall be deemed to be against equity and good conscience if the determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual. (See §§ 405.330–405.332 for conditions under which payment may be made for items or services furnished after October 30, 1972 which are noncovered by reasons of § 405.310 (g) and (k).)

[41 FR 1493, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.356 Principles applied in waiver of adjustment or recovery.

The principles applied in determining waiver of adjustment or recovery (§ 405.355) are the applicable principles of § 405.358 and 20 CFR 404.507–404.509, 404.510a, and 404.512.

[61 FR 49271, Sept. 19, 1996]

§ 405.357 Notice of right to waiver consideration.

Whenever an initial determination is made that more than the correct