

Centers for Medicare & Medicaid Services, HHS

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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.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74810, Dec. 10, 2013]

§ 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, 1862, 1866, 1870, 1871, 1879 and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395y, 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.

EDITORIAL NOTE: Nomenclature changes to subpart C of part 405 appear at 76 FR 5961, Feb. 2, 2011.

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 must, 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 fifth 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; 78 FR 74810, Dec. 10, 2013]

§ 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 at 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 will be deemed to be against equity and good conscience if the incorrect payment was made for items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act and if the determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual.

[41 FR 1493, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977; 78 FR 74810, Dec. 10, 2013]

§ 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

amount of payment has been made, notice of the provisions of section 1870(c) of the Act regarding waiver of adjustment or recovery shall be sent to the overpaid individual and to any other individual against whom adjustment or recovery of the overpayment is to be effected (see § 405.358).

[61 FR 49271, Sept. 19, 1996]

§ 405.358 When waiver of adjustment or recovery may be applied.

Section 1870(c) of the Act provides that there shall be no adjustment or recovery in any case where an incorrect payment under title XVIII (hospital and supplementary medical insurance benefits) has been made (including a payment under section 1814(e) of the Act with respect to an individual:

- (a) Who is without fault, and
- (b) Adjustment or recovery would either:
 - (1) Defeat the purposes of title II or title XVIII of the Act, or
 - (2) Be against equity and good conscience.

[61 FR 49271, Sept. 19, 1996]

§ 405.359 Liability of certifying or disbursing officer.

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person:

- (a) Where the adjustment or recovery of such amount is waived (see § 405.355), or
- (b) Where adjustment (see § 405.352) or recovery is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

SUSPENSION AND RECOUPMENT OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

§ 405.370 Definitions.

(a) For purposes of this subpart, the following definitions apply:

Credible allegation of fraud. A credible allegation of fraud is an allegation from any source, including but not limited to the following:

- (1) Fraud hotline tips verified by further evidence
- (2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

Fraud hotline tip. A complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Medicare contractor. Unless the context otherwise requires, includes, but is not limited to the any of following:

- (1) A fiscal intermediary.
- (2) A carrier.
- (3) Program safeguard contractor.
- (4) Zone program integrity contractor.
- (5) Part A/Part B Medicare administrative contractor.

Offset. The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. (Examples are Public Health Service debts or Medicaid debts recovered by CMS).

Recoupment. The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Resolution of an investigation. An investigation of credible allegations of fraud will be considered resolved when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence to support the allegations of fraud.

Suspension of payment. The withholding of payment by a Medicare contractor from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists, or until the resolution of an investigation of a credible allegation of fraud.

(b) For purposes of §§ 405.378 and 405.379, the following terms apply:

Appellant means the beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does

not in itself convey standing to appeal the determination in question.

Fiscal intermediary means an organization that has entered into a contract with CMS in accordance with section 1816 of the Act and is authorized to make determinations and payments for Part A of title XVIII of the Act, and Part B provider services as specified in § 421.5(c) of this chapter.

Medicare Appeals Council means the council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

Medicare contractor, unless the context otherwise requires, includes, but is not limited to, a fiscal intermediary, carrier, recovery audit contractor, and Medicare administrative contractor.

Party means an individual or entity listed in § 405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination.

Qualified Independent Contractor (QIC) means an entity which contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978.

Remand means to vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

Vacate means to set aside a previous action.

[61 FR 63745, Dec. 2, 1996, as amended at 74 FR 47468, Sept. 16, 2009; 76 FR 5961, Feb. 2, 2011; 86 FR 6093, Jan. 19, 2021]

§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) *General rules*—Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be one of the following:

(1) Suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor possesses reliable information that an overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination.

(2) In cases of suspected fraud, suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments.

(3) Offset or recouped, in whole or in part, by a Medicare contractor if the Medicare contractor or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

(4) Suspended, in whole or in part, by CMS or a Medicare contractor if the provider or supplier has been subject to a Medicaid payment suspension under § 455.23(a)(1) of this chapter.

(b) *Good cause exceptions applicable to payment suspensions.* (1) CMS may find that good cause exists not to suspend payments or not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud if—

(i) OIG or other law enforcement agency has specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation;

(ii) It is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or part as to cause a danger to life or health;

(iii) It is determined that other available remedies implemented by CMS or a Medicare contractor more effectively or quickly protect Medicare funds than would implementing a payment suspension; or

(iv) CMS determines that a payment suspension or a continuation of a payment suspension is not in the best interests of the Medicare program.

(2) Every 180 days after the initiation of a suspension of payments based on credible allegations of fraud, CMS will—

(i) Evaluate whether there is good cause to not continue such suspension under this section; and

(ii) Request a certification from the OIG or other law enforcement agency that the matter continues to be under

investigation warranting continuation of the suspension.

(3) Good cause not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud must be deemed to exist if a payment suspension has been in effect for 18 months and there has not been a resolution of the investigation, except CMS may extend a payment suspension beyond that point if—

(i) The case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties); or such administrative action is pending or

(ii) The Department of Justice submits a written request to CMS that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal or civil action or both or based on a pending criminal or civil action or both. At a minimum, the request must include the following:

(A) Identification of the entity under suspension.

(B) The amount of time needed for continued suspension in order to conclude the criminal or civil proceeding or both.

(C) A statement of why or how criminal or civil action or both may be affected if the requested extension is not granted.

(c) *Steps necessary for suspension of payment, offset, and recoupment.* (1) Except as provided in paragraphs (d) and (e) of this section, CMS or the Medicare contractor suspends payments only after it has complied with the procedural requirements set forth at § 405.372.

(2) The Medicare contractor offsets or recoups payments only after it has complied with the procedural requirements set forth at § 405.373.

(d) *Suspension of payment in the case of unfiled cost reports.* (1) If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled cost report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

(e) *Suspension of payment in the case of unfiled hospice cap determination reports.*

(1) If a provider has failed to timely file an acceptable hospice cap determination report, payment to the provider is immediately suspended in whole or in part until a cap determination report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled hospice cap determination report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

[76 FR 5961, Feb. 2, 2011, as amended at 79 FR 50509, Aug. 22, 2014; 84 FR 47852, Sept. 10, 2019]j

§ 405.372 Proceeding for suspension of payment.

(a) *Notice of intention to suspend*—(1) *General rule.* Except as provided in paragraphs (a)(2) through (a)(4) of this section, if the Medicare contractor, or CMS has determined that a suspension of payments under § 405.371(a)(1) should be put into effect, the Medicare contractor must notify the provider or supplier of the intention to suspend payments, in whole or in part, and the reasons for making the suspension.

(2) *Failure to furnish information.* The notice requirement of paragraph (a)(1) of this section does not apply if the Medicare contractor suspends payments to a provider or supplier in accordance with section 1815(a) or section 1833(e) of the Act, respectively, because the provider or supplier has failed to submit information requested by the Medicare contractor that is needed to determine the amounts due the provider or supplier. (See § 405.371(c) concerning failure to file timely acceptable cost reports.)

(3) *Harm to trust funds.* A suspension of payment may be imposed without prior notice if CMS, the intermediary, or carrier determines that the Medicare Trust Funds would be harmed by giving prior notice. CMS may base its determination on an intermediary's or carrier's belief that giving prior notice would hinder the possibility of recovering the money.

(4) *Fraud.* If the intended suspension of payment involves credible allegations of fraud under § 405.371(a)(2), CMS—

(i) In consultation with OIG and, as appropriate, the Department of Justice, determines whether to impose the suspension and if prior notice is appropriate;

(ii) Directs the Medicare contractor as to the timing and content of the notification to the provider or supplier; and

(iii) Is the real party in interest and is responsible for the decision.

(b) *Rebuttal*—(1) *If prior notice is required.* If prior notice is required under paragraph (a) of this section, the Medicare contractor must give the provider or supplier an opportunity for rebuttal in accordance with § 405.374. If a rebuttal statement is received within the specified time period, the suspension of payment goes into effect on the date stated in the notice, and the procedures and provisions set forth in § 405.375 apply. If by the end of the period specified in the notice no statement has been received, the suspension goes into effect automatically, and the procedures set forth in paragraph (c) of this section are followed.

(2) *If prior notice is not required.* If, under the provisions of paragraphs (a)(2) through (a)(4) of this section, a suspension of payment is put into effect without prior notice to the provider or supplier, the Medicare contractor must, once the suspension is in effect, give the provider or supplier an opportunity to submit a rebuttal statement as to why the suspension should be removed.

(c) *Subsequent action.* (1) If a suspension of payment is put into effect under § 405.371(a)(1), CMS or the Medicare contractor takes timely action after the suspension to obtain the additional information it may need to make a determination as to whether an overpayment exists or the payments may be made.

(i) CMS or the Medicare contractor makes all reasonable efforts to expedite the determination.

(ii) As soon as the determination is made, CMS or the Medicare contractor informs the provider or supplier and, if appropriate, the suspension is rescinded or any existing recoupment or offset is adjusted to take into account the determination.

(2)(i) If a suspension of payment is based upon credible allegations of fraud in accordance with § 405.371(a)(2), subsequent action must be taken by CMS or the Medicare contractor to make a determination as to whether an overpayment exists.

(ii) The rescission of the suspension and the issuance of a final overpayment determination to the provider or supplier may be delayed until resolution of the investigation.

(d) *Duration of suspension of payment*—(1) *General rule.* Except as provided in paragraphs (d)(2) and (d)(3) of this section, a suspension of payment is limited to 180 days, starting with the date the suspension begins.

(2) *180-day extension.* (i) An intermediary, a carrier, or, in cases of fraud and misrepresentation, OIG or a law enforcement agency, may request a one-time only extension of the suspension period for up to 180 additional days if it is unable to complete its examination of the information or investigation, as appropriate, within the 180-day time limit. The request must be submitted in writing to CMS.

(ii) Upon receipt of a request for an extension, CMS notifies the provider or supplier of the requested extension. CMS then either extends the suspension of payment for up to an additional 180 days or determines that the suspended payments are to be released to the provider or supplier.

(3) *Exceptions to the time limits.* (i) The time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply if the suspension of payments is based upon credible allegations of fraud under § 405.371(a)(2).

(ii) Although the time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply to suspensions based on credible allegations of fraud, all suspensions of payment in accordance with § 405.371(a)(2) will be temporary and will not continue after the resolution of an investigation, unless a suspension is warranted because of reliable evidence of an overpayment or that the payments to be made may not be correct, as specified in § 405.371(a)(1).

(e) *Disposition of suspended payments.* Payments suspended under the authority of § 405.371(a) are first applied to reduce or eliminate any overpayments determined by the Medicare contractor, or CMS, including any interest assessed under the provisions of § 405.378, and then applied to reduce any other obligation to CMS or to HHS. In the absence of a legal requirement that the excess be paid to another entity, the excess is released to the provider or supplier.

[61 FR 63746, Dec. 2, 1996, as amended at 76 FR 5962, Feb. 2, 2011]

§ 405.373 Proceeding for offset or recoupment.

(a) *General rule.* Except as specified in paragraphs (b) and (f) of this section, if the Medicare Administrative Contractor or CMS has determined that an offset or recoupment of payments under § 405.371(a)(3) should be put into effect, the Medicare Administrative Contractor must—

(1) Notify the provider or supplier of its intention to offset or recoup payment, in whole or in part, and the reasons for making the offset or recoupment; and

(2) Give the provider or supplier an opportunity for rebuttal in accordance with § 405.374.

(b) *Exception to recouping payment.* Paragraph (a) of this section does not apply if the Medicare Administrative Contractor, after furnishing a provider a written notice of the amount of program reimbursement in accordance with § 405.1803, recoups payment under paragraph (c) of § 405.1803. (For provider rights in this circumstance, see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843.)

(c) *Actions following receipt of rebuttal statement.* If a provider or supplier submits, in accordance with § 405.374, a statement as to why an offset or recoupment should not be put into effect on the date specified in the notice, the Medicare contractor must comply with the time limits and notification requirements of § 405.375.

(d) *No rebuttal statement received.* If, by the end of the time period specified in the notice, no statement has been received, the recoupment or offset goes into effect automatically.

(e) *Duration of recoupment or offset.* Except as provided in § 405.379, if a recoupment or offset is put into effect, it remains in effect until the earliest of the following:

(1) The overpayment and any assessed interest are liquidated.

(2) The Medicare contractor obtains a satisfactory agreement from the provider or supplier for liquidation of the overpayment.

(3) The Medicare contractor, on the basis of subsequently acquired evidence or otherwise, determines that there is no overpayment.

(f) *Exception to offset or recoupment of payments for shared Taxpayer Identification Number.* Paragraph (a) of this section does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services or supplier share the same Taxpayer Identification Number.

[61 FR 63747, Dec. 2, 1996, as amended at 74 FR 47468, Sept. 16, 2009; 81 FR 80551, Nov. 15, 2016]

§ 405.374 Opportunity for rebuttal.

(a) *General rule.* If prior notice of the suspension of payment, offset, or recoupment is given under § 405.372 or § 405.373, the Medicare contractor must give the provider or supplier an opportunity, before the suspension, offset, or recoupment takes effect, to submit any statement (to include any pertinent information) as to why it should not be put into effect on the date specified in the notice. Except as provided in paragraph (b) of this section, the provider or supplier has at least 15 days following the date of notification to submit the statement.

(b) *Exception.* The Medicare contractor may for cause—

(1) Impose a shorter period for rebuttal; or

(2) Extend the time within which the statement must be submitted.

[61 FR 63747, Dec. 2, 1996]

§ 405.375 Time limits for, and notification of, administrative determination after receipt of rebuttal statement.

(a) *Submission and disposition of evidence.* If the provider or supplier submits a statement, under § 405.374, as to why a suspension of payment, offset, or recoupment should not be put into effect, or, under § 405.372(b)(2), why a suspension should be terminated, CMS, the intermediary, or carrier must within 15 days, from the date the statement is received, consider the statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and determine whether the facts justify the suspension, offset, or recoupment or, if already initiated, justify the termination of the suspension, offset, or recoupment. Suspension, offset, or recoupment is not delayed beyond the date stated in the notice in order to review the statement.

(b) *Notification of determination.* The Medicare contractor must send written notice of the determination made under paragraph (a) of this section to the provider or supplier. The notice must—

(1) In the case of offset or recoupment, contain rationale for the determination; and

(2) In the case of suspension of payment, contain specific findings on the conditions upon which the suspension is initiated, continued, or removed and an explanatory statement of the determination.

(c) *Determination is not appealable.* A determination made under paragraph (a) of this section is not an initial determination and is not appealable.

[61 FR 63747, Dec. 2, 1996]

§ 405.376 Suspension and termination of collection action and compromise of claims for overpayment.

(a) *Basis and purpose.* This section contains requirements and procedures for the compromise of, or suspension or termination of collection action on, claims for overpayments against a provider or a supplier under the Medicare program. It is adopted under the authority of the Federal Claims Collection Act (31 U.S.C. 3711). Collection and compromise of claims against Medicare

beneficiaries are explained at 20 CFR 404.515.

(b) *Definitions.* As used in this section, *debtor* means a provider of services or a physician or other supplier of services that has been overpaid under title XVIII of the Social Security Act. It includes an individual, partnership, corporation, estate, trust, or other legal entity.

(c) *Basic conditions.* A claim for recovery of Medicare overpayments against a debtor may be compromised, or collection action on it may be suspended or terminated, by the Centers for Medicare & Medicaid Services (CMS) if:

(1) The claim does not exceed \$100,000, or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest; and

(2) There is no indication of fraud, the filing of a false claim, or misrepresentation on the part of the debtor or any director, partner, manager, or other party having an interest in the claim.

(d) *Basis for compromise.* A claim may be compromised for one or more of the following reasons:

(1) The debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount within a reasonable time;

(2) The debtor refuses to pay the claim in full and the United States is unable to collect the full amount within a reasonable time by legal proceedings;

(3) There is real doubt the United States can prove its case in court; or

(4) The cost of collecting the claim does not justify enforced collection of the full amount.

(e) *Basis for termination of collection action.* Collection action may be terminated for one or more of the following reasons:

(1) The United States cannot enforce collection of any significant sum;

(2) The debtor cannot be located, there is no security to be liquidated, the statute of limitations has run, and the prospects of collecting by offset are too remote to justify retention of the claim;

(3) The cost of further collection action is likely to exceed any recovery;

(4) It is determined the claim is without merit; or

(5) Evidence to substantiate the claim is no longer available.

(f) *Basis for suspension of collection action.* Collection action may be suspended for either of the following reasons if future collection action is justified based on potential productivity, including foreseeable ability to pay, and size of claim:

(1) The debtor cannot be located; or

(2) The debtor is unable to make payments on the claim or to fulfill an acceptable compromise.

(g) *Factors considered.* In determining whether a claim will be compromised, or collection action terminated or suspended, CMS will consider the following factors:

(1) Age and health of the debtor, present and potential income, inheritance prospects, possible concealment or fraudulent transfer of assets, and the availability of assets which may be reached by enforced collection proceedings, for compromise under paragraph (d)(1) of this section, termination under paragraph (e)(1) of this section, and suspension under paragraph (f)(2) of this section;

(2) Applicable exemptions available to a debtor and uncertainty concerning the price of the property in a forced sale, for compromise under paragraph (d)(2) of this section and termination under paragraph (e)(1) of this section; and

(3) The probability of proving the claim in court, the probability of full or partial recovery, the availability of necessary evidence, and related pragmatic considerations, for compromise under paragraph (d)(3) of this section.

(h) *Amount of compromise.* The amount accepted in compromise will be reasonable in relation to the amount that can be recovered by enforced collection proceedings.

Consideration shall be given to the following:

(1) The exemptions available to the debtor under State or Federal law;

(2) The time necessary to collect the overpayment;

(3) The litigative probabilities involved; and

(4) The administrative and litigative costs of collection where the cost of

collecting the claim is a basis for compromise.

(i) *Payment of compromise—(1) Time and manner.* Payment of the amount that CMS has agreed to accept as a compromise in full settlement of a Medicare overpayment claim must be made within the time and in the manner prescribed by CMS. An overpayment claim is not compromised or settled until the full payment of the compromised amount has been made within the time and in the manner prescribed by CMS.

(2) *Failure to pay compromised amount.* Failure of the debtor or the estate to make payment as provided by the compromise reinstates the full amount of the overpayment claim, less any amounts paid prior to the default.

(j) *Effect of compromise, or suspension, or termination of collection action.* Any action taken by CMS under this section regarding the compromise of an overpayment claim, or termination or suspension of collection action on an overpayment claim, is not an initial determination for purposes of the appeal procedures under subparts G, H, and R of this part.

[43 FR 59381, Dec. 20, 1978, as amended at 57 FR 56998, Dec. 2, 1992. Redesignated and amended at 61 FR 63745, 63747, Dec. 2, 1996]

§ 405.377 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* This section implements section 1885 of the Act, which provides for withholding Medicare payments to certain Medicaid providers that have not arranged to repay Medicaid overpayments as determined by the Medicaid State agency or have failed to provide information necessary to determine the amount (if any) of overpayments.

(b) *When withholding may be used.* CMS may withhold Medicare payment to offset Medicaid overpayments that a Medicaid agency has been unable to collect if—

(1) The Medicaid agency has followed the procedure specified in § 447.31 of this chapter; and

(2) The institution or person is one described in paragraph (c) of this section and either—

(i) Has not made arrangements satisfactory to the Medicaid agency to repay the overpayment; or

(ii) Has not provided information to the Medicaid agency necessary to enable the agency to determine the existence or amount of Medicaid overpayment.

(c) *Institutions or persons affected.* Withholding under paragraph (b) of this section may be made with respect to any of the following entities that has or had in effect an agreement with a Medicaid agency to furnish services under an approved Medicaid State plan:

(1) An institutional provider that has in effect an agreement under section 1866 of the Act. (Part 489 (Provider and Supplier Agreements) implements section 1866 of the Act.)

(2) A physician or supplier that has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act. (Section 424.55 sets forth the conditions a supplier agrees to in accepting assignment.)

(d) *Amount to be withheld.* (1) CMS contacts the appropriate Medicare contractor to determine the amount of Medicare payment to which the institution or person is entitled.

(2) CMS may require the Medicare contractor to withhold Medicare payments to the institution or person by the lesser of the following amounts:

(i) The amount of the Medicare payments to which the institution or person would otherwise be entitled.

(ii) The total Medicaid overpayment to the institution or person.

(e) *Notice of withholding.* If CMS intends to withhold payments under this section, it notifies by certified mail, return receipt requested, the institution or person and the appropriate Medicare contractor of the intention to withhold Medicare payments and follows the procedure in § 405.374. The notice includes—

(1) Identification of the institution or person; and

(2) The amount of Medicaid overpayment to be withheld from payments to which the institution or person would otherwise be entitled under Medicare.

(f) *Termination of withholding.* CMS terminates the withholding if—

(1) The Medicaid overpayment is completely recovered;

(2) The institution or person enters into an agreement satisfactory to the Medicaid agency to repay the overpayment; or

(3) The Medicaid agency determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(g) *Disposition of funds withheld.* CMS releases amounts withheld under this section to the Medicaid agency to be applied against the Medicaid overpayment made by the State agency.

[61 FR 63747, Dec. 2, 1996]

§ 405.378 Interest charges on overpayment and underpayments to providers, suppliers, and other entities.

(a) *Basis and purpose.* This section, which implements sections 1815(d), 1833(j) and 1893(f)(2)(B) of the Act and common law, and authority granted under the Federal Claims Collection Act, provides for the charging and payment of interest on overpayments and underpayments to Medicare providers, suppliers, HMOs, competitive medical plans (CMPs), and health care prepayment plans (HCPPs).

(b) *Basic rules.* (1) CMS will charge interest on overpayments, and pay interest on underpayments, to providers and suppliers of services (including physicians and other practitioners), except as specified in paragraphs (f) and (h) of this section.

(2) Except as provided in paragraph (j) of this section, interest accrues from the date of the final determination as defined in paragraph (c) of this section, and either is charged on the overpayment balance or paid on the underpayment balance for each full 30-day period that payment is delayed.

(c) *Definition of final determination.* (1) For purposes of this section, any of the following constitutes a final determination:

(i) A Notice of Amount of Program Reimbursement (NPR) is issued, as discussed in §§ 405.1803, 417.576, and 417.810, and either—

(A) A written demand for payment is made; or

(B) A written determination of an underpayment is made by the intermediary after a cost report is filed.

(ii) In cases in which an NPR is not used as a notice of determination (that

is, primarily under part B), one of the following constitutes a final determination—

(A) A written determination that an overpayment exists and a written demand for payment; or

(B) A written determination of an underpayment.

(iii) Other examples of cases in which an NPR is not used are carrier reasonable charge determinations under subpart E of this part, interim cost settlements made for HMOs, CMPs, and HCPPs under §§ 417.574 and 417.810(e) of this chapter, and initial retroactive adjustment determinations under § 413.64(f)(2) of this chapter. In the case of interim cost settlements and initial retroactive adjustment determinations, if the debtor does not dispute the adjustment determination within the timeframe designated in the notice of the determination (generally at least 15 days), a final determination is deemed to have been made. If the provider or supplier does dispute portions of the determination, a final determination is deemed to have been made on those portions when the intermediary issues a new determination in response to the dispute.

(iv) The due date of a timely-filed cost report that indicates an amount is due CMS, and is not accompanied by payment in full. (If an additional overpayment or underpayment is determined by the carrier or intermediary, a final determination on the additional amount is made in accordance with paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii), of this section.)

(v) With respect to a cost report that is not filed on time, the day following the date the cost report was due (plus a single extension of time not to exceed 30 days if granted for good cause), until the time as a cost report is filed. (When the cost report is subsequently filed, there is an additional determination as specified in paragraphs (c)(1)(i), (ii), (iii), or (iv) of this section.)

(2) Except as required by any subsequent administrative or judicial reversal and specifically as provided in paragraphs (i) and (j) of this section, interest accrues from the date of final determination as specified in this section.

(d) *Rate of interest.* (1) The interest rate on overpayments and underpayments is the higher of—

(i) The rate as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of final determination as defined in paragraph (c) of this section (this rate is published quarterly in the FEDERAL REGISTER by the Department under 45 CFR 30.13(a)); or

(ii) The current value of funds rate (this rate is published annually in the FEDERAL REGISTER by the Secretary of the Treasury, subject to quarterly revisions).

(2) [Reserved]

(e) *Accrual of interest.* (1) If a cost report is filed that does not indicate an amount is due CMS but the intermediary makes a final determination that an overpayment exists, or if a carrier makes a final determination that an overpayment to a physician or supplier exists, interest will accrue beginning with the date of such final determination. Interest will continue to accrue during periods of administrative and judicial appeal and until final disposition of the claim.

(2)(i) If a cost report is filed and indicates that an amount is due CMS, interest on the amount due will accrue from the due date of the cost report unless—

(A) Full payment on the amount due accompanies the cost report; or

(B) The provider and the intermediary agree in advance to liquidate the overpayment through a reduction in interim payments over the next 30-day period.

(ii) If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination.

(iii) The interest rate on each of the final determinations of an overpayment will be the rate of interest in effect on the date the determination is made.

(3) In the case of a cost report that is not filed on time, interest also will accrue on a determined overpayment from the day following the due date of the report (plus a single extension of time not to exceed 30 days if granted

for good cause, as specified in § 413.24(f) of this chapter, to the time the cost report is filed.

(4) If an intermediary or a carrier makes a final determination that an underpayment exists, interest to the provider or the supplier will accrue from the date of notification of the underpayment.

(f) *Waiver of interest charges.* (1) When an intermediary or a carrier makes a final determination that an overpayment or underpayment exists, as specified in paragraphs (e)(1), (e)(2)(ii), and (e)(4)—

(i) Interest charges will be waived if the overpayment or underpayment is completely liquidated within 30 days from the date of the final determination.

(ii) CMS may waive interest charges if it determines that the administrative cost of collecting them exceeds the interest charges.

(2) Interest will not be waived for that period of time during which the cost report was due but remained unfiled for more than 30 days, as specified in paragraph (e)(3) of this section.

(g) *Rules applicable to partial payments.* If an overpayment is repaid in installments or recouped by withholding from several payments due the provider or supplier of services—

(1) Each payment or recoupment will be applied first to accrued interest and then to the principal; and

(2) After each payment or recoupment, interest will accrue on the remaining unpaid balance.

(h) *Nonallowable cost.* As specified in §§ 412.113 and 413.153 of this chapter, interest accrued on overpayments and interest on funds borrowed specifically to repay overpayments are not considered allowable costs, up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(See § 413.153(a)(2) of this chapter for exceptions based on administrative or judicial reversal.)

(i) *Exceptions to applicability.* (1) The provisions of this section do not apply to the time period for which interest is payable under § 413.64(j) of this chapter because the provider seeks judicial review of a decision of the Provider Re-

imbursement Review Board, or a subsequent reversal, affirmance, or modification of that decision by the Administrator. Prior to that time, until the provider seeks judicial review, interest accrues at the rate specified in this section on outstanding unpaid balances resulting from final determinations as defined in paragraph (c) of this section.

(2) If an overpayment or an underpayment determination is reversed administratively or judicially, and the reversal is no longer subject to appeal, appropriate adjustments will be made with respect to the overpayment or underpayment and the amount of interest charged.

(j) *Special rule for provider or supplier overpayments subject to § 405.379.* If an overpayment determination subject to the limitation on recoupment under § 405.379 is reversed in whole or in part by an Administrative Law Judge (ALJ) or at subsequent administrative or judicial levels of appeal and if funds have been recouped and retained by the Medicare contractor, interest will be paid to the provider or supplier as follows:

(1) The applicable rate of interest is that provided in paragraph (d) of this section.

(2) The interest rate in effect on the date the ALJ, the Medicare Appeals Council, the Federal district court or subsequent appellate court issues a decision reversing the overpayment determination in whole or in part is the rate used to calculate the interest due the provider or supplier.

(3) Interest will be calculated as follows:

(i) Interest will be paid on the principal amount recouped only.

(ii) Interest will be calculated on a simple rather than a compound basis.

(iii) Interest will be calculated in full 30-day periods and will not be payable on amounts recouped for any periods of less than 30 days in which the Medicare contractor had possession of the funds.

(iv) In calculating the period in which the amount was recouped, days in which the ALJ's adjudication period to conduct a hearing are tolled under 42 CFR 405.1014 shall not be counted.

(v) In calculating the period in which the amount was recouped, days in which the Medicare Appeals Council's

adjudication period to conduct a review are tolled under 42 CFR 405.1106 shall not be counted.

(4) If the decision by the ALJ, Medicare Appeals Council, Federal district court or a subsequent Federal reviewing court, reverses the overpayment determination, as modified by prior levels of administrative or judicial review, in part, the Medicare contractor in effectuating the decision may allocate recouped monies to that part of the overpayment determination affirmed by the decision. Interest will be paid to the provider or supplier on recouped amounts that remain after this allocation in accordance with this paragraph (j) of this section.

[47 FR 54814, Dec. 6, 1982, as amended at 49 FR 36102, Sept. 14, 1984; 49 FR 44472, Nov. 7, 1984; 51 FR 34792, Sept. 30, 1986; 56 FR 31336, July 10, 1991. Redesignated at 61 FR 63745, Dec. 2, 1996; 69 FR 45607, July 30, 2004; 74 FR 47468, Sept. 16, 2009]

§ 405.379 Limitation on recoupment of provider and supplier overpayments.

(a) *Basis and purpose.* This section implements section 1893(f)(2)(A) of the Act which limits recoupment of Medicare overpayments if a provider of services or supplier seeks a reconsideration until a decision is rendered by a Qualified Independent Contractor (QIC). This section also limits recoupment of Medicare overpayments when a provider or supplier seeks a redetermination until a redetermination decision is rendered.

(b) *Overpayments subject to limitation.*

(1) This section applies to overpayments that meet the following criteria:

(i) Is one of the following types of overpayments:

(A) Post-pay denial of claims for benefits under Medicare Part A which is determined and for which a written demand for payment has been made on or after November 24, 2003; or

(B) Post-pay denial of claims for benefits under Medicare Part B which is determined and for which a written demand for payment has been made on or after October 29, 2003; or

(C) Medicare Secondary Payer (MSP) recovery where the provider or supplier received a duplicate primary payment and for which a written demand for

payment was issued on or after October 10, 2003; or

(D) Medicare Secondary Payer (MSP) recovery based on the provider's or supplier's failure to file a proper claim with the third party payer plan, program, or insurer for payment and, if Part A, demanded on or after November 24, 2003, or, if Part B, demanded on or after October 29, 2003; and

(ii) The provider or supplier can appeal the overpayment as a revised initial determination under the Medicare claims appeal process at 42 CFR parts 401 and 405 or as an initial determination for provider/supplier MSP duplicate primary payment recoveries.

(2) This section does not apply to all other overpayments including, but not limited to, the following:

(i) All Medicare Secondary Payer recoveries except those expressly identified in paragraphs (b)(1)(i)(C) and (D) of this section;

(ii) Beneficiary overpayments; and

(iii) Overpayments that arise from a cost report determination and are appealed under the provider reimbursement process of 42 CFR part 405 Subpart R—Provider Reimbursement Determinations and Appeals.

(c) *Rules of construction.* (1) For purposes of this section, what constitutes a valid and timely request for a redetermination is to be determined in accordance with § 405.940 through § 405.958.

(2) For purposes of this section, what constitutes a valid and timely request for a reconsideration is to be determined in accordance with § 405.960 through § 405.978.

(d) *General rules.* (1) Medicare contractors can begin recoupment no earlier than 41 days from the date of the initial overpayment demand but shall cease recoupment of the overpayment in question, upon receipt of a timely and valid request for a redetermination of an overpayment. If the recoupment has not yet gone into effect, the contractor shall not initiate recoupment.

(2) If the redetermination decision is an affirmation in whole or in part of the overpayment determination, recoupment may be initiated or resumed in accordance with paragraph (e) of this section.

(3) Upon receipt of a timely and valid request for a reconsideration of an

overpayment, the Medicare contractor shall cease recoupment of the overpayment in question. If the recoupment has not yet gone into effect, the contractor must not initiate recoupment.

(4) The contractor may initiate or resume recoupment following action by the QIC in accordance with paragraph (f) of this section.

(5) If the provider or supplier subsequently appeals the overpayment to the ALJ, the Medicare Appeals Council, or Federal court, recoupment remains in effect as provided in § 405.373(e).

(6) If an overpayment determination is appealed and recoupment stopped, the contractor may continue to recoup other overpayments owed by the provider or supplier in accordance with this section.

(7) Amounts recouped prior to a reconsideration decision may be retained by the Medicare contractor in accordance with paragraph (g) of this section.

(8) If either the redetermination or reconsideration decision is a full reversal of the overpayment determination or if the overpayment determination is reversed in whole or in part at subsequent levels of administrative or judicial appeal, adjustments shall be made with respect to the overpayment and the amount of interest charged.

(9) Interest accrues and is payable in accordance with the provisions of § 405.378.

(e) *Initiating or resuming recoupment after redetermination decision.* (1) Recoupment that has been deferred or stopped may be initiated or resumed if the debt (remaining unpaid principal balance and interest) has not been satisfied in full and the provider or supplier has been afforded the opportunity for rebuttal in accordance with the requirements of § 405.373 through § 405.375. Recoupment may be resumed under any of the following circumstances:

(i) Immediately upon receipt by the Medicare contractor of the provider's or supplier's request for a withdrawal of a request for a redetermination in accordance with § 405.952(a).

(ii) On the 60th calendar day after the date of the notice of redetermination issued under § 405.956 if the redetermination decision is an affirmation in

whole of the overpayment determination in question.

(iii) On the 60th calendar day after the date of the written notice to the provider or supplier of the revised overpayment amount, if the redetermination decision is an affirmation in part, which has the effect of reducing the amount of the overpayment.

(2) Notwithstanding paragraphs (e)(i), (ii) and (iii) of this section, recoupment must not be resumed, or if resumed, must cease upon receipt of a timely and valid request for a reconsideration by the QIC.

(f) *Initiating or resuming recoupment following action by the QIC on the reconsideration request.* (1) Recoupment may be initiated or resumed upon action by the QIC subject to the following limitations:

(i) The provider or supplier has been afforded the opportunity for rebuttal in accordance with the requirements of § 405.373 through § 405.375; and

(ii) The debt (remaining unpaid principal balance and interest) has not been satisfied in full; and

(iii) If the action by the QIC is the notice of the reconsideration, the reconsideration decision either affirms in whole or in part the overpayment determination, including the redetermination, in question.

(2) For purposes of this paragraph (f), the action by the QIC on the reconsideration request is the earliest to occur of the following:

(i) The QIC mails or otherwise transmits written notice of the dismissal of the reconsideration request in its entirety in accordance with § 405.972; or

(ii) The QIC receives a timely and valid request to withdraw the request for the reconsideration in accordance with § 405.972; or

(iii) The QIC transmits written notice of the reconsideration in accordance with § 405.976; or

(iv) The QIC notifies the parties in writing that the reconsideration is being escalated to an ALJ in accordance with § 405.970.

(g) *Disposition of funds recouped.* (1) If the Medicare contractor recouped funds before a timely and valid request for a redetermination was received, the amount recouped may be retained and applied first to accrued interest and

then to reduce or eliminate the principal balance of the overpayment subject to the following:

(i) If the redetermination results in a reversal, the amount recouped may be applied to any other debt, including interest, owed by the provider or supplier before any excess is released to the provider.

(ii) If the redetermination results in a partial reversal and the decision reduces the overpayment plus assessed interest below the amount already recouped, the excess may be applied to any other debt, including interest, owed by the provider or supplier before any excess is released to the provider or supplier.

(iii) If the redetermination results in an affirmation and the provider or supplier subsequently requests a reconsideration, the Medicare contractor may retain the amount recouped and apply the funds first to accrued interest and then to outstanding principal pending action by the QIC on the reconsideration request.

(2) If the Medicare contractor also recouped funds in accordance with paragraph (e) of this section, the amount recouped may be retained by the Medicare contractor and applied first to accrued interest and then to reduce or eliminate the outstanding principal balance pending action by the QIC on the reconsideration request.

(3) If the action by the QIC is a dismissal, receipt of a withdrawal, a notice that the reconsideration is being escalated to an ALJ, or a reconsideration which affirms in whole the overpayment determination, including the redetermination, in question, the amount recouped is applied to interest first, then to reduce the outstanding principal balance and recoupment may be resumed as provided under paragraph (f) of this section.

(4) If the action by the QIC is a reconsideration, which reverses in whole the overpayment determination, including the redetermination, in question, the amount recouped may be applied to any other debt, including interest, owed by the provider or supplier to CMS or to HHS before any excess is released to the provider or supplier.

(5) If the action by the QIC is a reconsideration which results in a partial re-

versal and the decision reduces the overpayment plus assessed interest below the amount already recouped, the excess may be applied to any other debt, including interest, owed by the provider or supplier to CMS or to HHS before any excess is released to the provider or supplier.

(h) *Relationship to extended repayment schedules.* Notwithstanding § 401.607 (c)(2)(v) of this chapter regarding an extended repayment schedule (ERS), a provider or supplier will not be deemed in default if recoupment of an overpayment is not effectuated or stopped in accordance with this section, and the following conditions are met:

(1) The provider or supplier has been granted an ERS under § 401.607(c) of this chapter.

(2) The ERS has been granted for an overpayment that is listed in paragraph (b) of this section.

(3) The provider or supplier has submitted a valid and timely request to the Medicare contractor for a redetermination of the overpayment in accordance with §§ 405.940 through 405.958 or reconsideration of the overpayment in accordance with §§ 405.960 through 405.978.

[74 FR 47469, Sept. 16, 2009]

REPAYMENT OF SCHOLARSHIPS AND LOANS

§ 405.380 Collection of past-due amounts on scholarship and loan programs.

(a) *Basis and purpose.* This section implements section 1892 of the Act, which authorizes the Secretary to deduct from Medicare payments for services amounts considered as past-due obligations under the National Health Service Corps Scholarship program, the Physician Shortage Area Scholarship program, and the Health Education Assistance Loan program.

(b) *Offsetting against Medicare payment.* (1) Medicare carriers and intermediaries offset against Medicare payments in accordance with the signed repayment agreement between the Public Health Service and individuals who have breached their scholarship or loan obligations and who—

(i) Accept Medicare assignment for services;

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(ii) Are employed by or affiliated with a provider, HMO, or Competitive Medical Plan (CMP) that receives Medicare payment for services; or

(iii) Are members of a group practice that receives Medicare payment for services.

(2) For purposes of this section, “provider” includes all entities eligible to receive Medicare payment in accordance with an agreement under section 1866 of the Act.

(c) *Beginning of offset.* (1) The Medicare carrier offsets Medicare payments beginning six months after it notifies the individual or the group practice of the amount to be deducted and the particular individual to whom the deductions are attributable.

(2) The Medicare intermediary offsets payments beginning six months after it notifies the provider, HMO, CMP or group practice of the amount to be deducted and the particular individuals to whom the deductions are attributable. Offset of payments is made in accordance with the terms of the repayment agreement. If the individual ceases to be employed by the provider, HMO, or CMP, or leaves the group practice, no deduction is made.

(d) *Refusal to offset against Medicare payment.* If the individual refuses to enter into a repayment agreement, or breaches any provision of the agreement, or if Medicare payment is insufficient to maintain the offset collection according to the agreed upon formula, then—

(1) The Department, within 30 days if feasible, informs the Attorney General; and

(2) The Department excludes the individual from Medicare until the entire past due obligation has been repaid, unless the individual is a sole community practitioner or the sole source of essential specialized services in a community and the State requests that the individual not be excluded.

[57 FR 19092, May 4, 1992]

Subpart D—Private Contracts

AUTHORITY: Secs. 1102, 1802, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395a, and 1395hh).

SOURCE: 63 FR 58901, Nov. 2, 1998, unless otherwise noted.

§ 405.400 Definitions.

For purposes of this subpart, the following definitions apply:

Beneficiary means an individual who is enrolled in Part B of Medicare.

Emergency care services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

Legal representative means one or more individuals who, as determined by applicable State law, has the legal authority to enter into the contract with the physician or practitioner on behalf of the beneficiary.

Opt-out means the status of meeting the conditions specified in § 405.410.

Opt-out period means, with respect to an affidavit that meets the requirements of § 405.420, a 2-year period beginning on the date the affidavit is signed, as specified by § 405.410(c)(1) or (2) as applicable, and each successive 2-year period unless the physician or practitioner properly cancels opt-out in accordance with § 405.445.

Participating physician means a “physician” as defined in this section who has signed an agreement to participate in Part B of Medicare.

Physician means a doctor of medicine; doctor of osteopathy; doctor of dental surgery or of dental medicine; doctor of podiatric medicine; or doctor of optometry who is legally authorized to practice medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, or optometry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions.

Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, mental health counselor, registered dietitian or nutrition professional, who is currently legally authorized to practice in that capacity by each State in