limits set forth in §401.136 and this section constitutes an exhaustion of the requester's administrative remedies.

§401.152 Court review.

Where the Administrator upon review affirms the denial of a request for records, in whole or in part, the requester may seek court review in the district court of the United States pursuant to 5 U.S.C. 552(a)(4)(B).

Subpart C [Reserved]

Subpart D—Reporting and Returning of Overpayments

SOURCE: 81 FR 7683, Feb. 12, 2016, unless otherwise noted.

§401.301 Basis and scope.

This subpart sets forth the policies and procedures for reporting and returning overpayments to the Medicare program for providers and suppliers of services under Parts A and B of title XVIII of the Act as required by section 1128J(d) of the Act.

§401.303 Definitions.

For purposes of this subpart—

Medicare contractor means a Part A/Part B Medicare Administrative Contractor (A/B MAC) or a Durable Medical Equipment Medicare Administrative Contractor (DME MAC).

Overpayment means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title.

Person means a provider (as defined in §400.202 of this chapter) or a supplier (as defined in §400.202 of this chapter).

§401.305 Requirements for reporting and returning of overpayments.

(a) *General.* (1) A person that has received an overpayment must report and return the overpayment in the form and manner set forth in this section.

(2) A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

(b) *Deadline for reporting and returning overpayments.* (1) A person who has received an overpayment must report and return the overpayment by the later of either of the following:

(i) The date which is 60 days after the date on which the overpayment was identified.

(ii) The date any corresponding cost report is due, if applicable.

(2) The deadline for returning overpayments will be suspended when the following occurs:

(i) OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.

(ii) CMS acknowledges receipt of a submission to the CMS Voluntary Self-Referral Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the CMS Voluntary Self-Referral Disclosure Protocol, or the person is removed from the CMS Voluntary Self-Referral Disclosure Protocol.

(iii) A person requests an extended repayment schedule as defined in §401.603 and will remain suspended until such time as CMS or one of its contractors rejects the extended repayment schedule request or the provider or supplier fails to comply with the terms of the extended repayment schedule.

(c) *Applicable reconciliation.* (1) The applicable reconciliation occurs when a cost report is filed; and

(2) In instances when the provider—

(i) Receives more recent CMS information on the SSI ratio, the provider is not required to return any overpayment resulting from the updated information until the final reconciliation of the provider's cost report occurs; or

(ii) Knows that an outlier reconciliation will be performed, the provider is

not required to estimate the change in reimbursement and return the estimated overpayment until the final reconciliation of that cost report.

(d) *Reporting.* (1) A person must use an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor to report an overpayment, except as provided in paragraph (d)(2) of this section. If the person calculates the overpayment amount using a statistical sampling methodology, the person must describe the statistically valid sampling and extrapolation methodology in the report.

(2) A person satisfies the reporting obligations of this section by making a disclosure under the OIG's Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol resulting in a settlement agreement using the process described in the respective protocol.

(e) *Enforcement.* Any overpayment retained by a person after the deadline for reporting and returning the overpayment specified in paragraph (b) of this section is an obligation for purposes of 31 U.S.C. 3729.

(f) *Lookback period.* An overpayment must be reported and returned in accordance with this section if a person identifies the overpayment, as defined in paragraph (a)(2) of this section, within 6 years of the date the overpayment was received.

Subpart E [Reserved]

Subpart F—Claims Collection and Compromise

SOURCE: 48 FR 39064, Aug. 29, 1983, unless otherwise noted.

§ 401.601 Basis and scope.

(a) *Basis.* This subpart implements the following statutory provisions:

(1) For CMS the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711), and conforms to the regulations (31 CFR parts 900–904) issued jointly by the Department of the Treasury and the Department of Justice that generally prescribe claims collection standards and procedures under the DCIA for the Federal government.

(2) Section 1893(f)(1) of the Act regarding the use of repayment plans.

(b) *Scope.* Except as provided in paragraphs (c) through (f) of this section, the regulations in this subpart describe CMS's procedures and standards for the collection of claims in any amount, and the compromise of, or the suspension or termination of collection action on, all claims for money or property that do not exceed $100,000 or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest, arising under any functions delegated to CMS by the Secretary.

(c) *Amount of claim.* CMS refers all claims that exceed $100,000 or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest, to the Department of Justice or the General Accounting Office for the compromise of claims, or the suspension or termination of collection action.

(d) *Related regulations*—(1) *Department regulations.* DHHS regulations applicable to CMS that generally implement the FCCA for the Department are located at 45 CFR part 30. These regulations apply only to the extent CMS regulations do not address a situation.

(2) *CMS regulations.* The following regulations govern specific debt management situations encountered by CMS and supplement this subpart:

(i) Claims against Medicare beneficiaries for the recovery of overpayments are covered in 20 CFR 404.515.

(ii) Adjustments in Railroad Retirement or Social Security benefits to recover Medicare overpayments to individuals are covered in §§ 405.350–405.358 of this chapter.

(iii) Claims against providers, physicians, or other suppliers of services for overpayments under Medicare and for assessment of interest are covered in §§ 405.377 and 405.378 of this chapter, respectively.

(iv) Claims against beneficiaries for unpaid hospital insurance or supplementary medical insurance premiums under Medicare are covered in § 408.110 of this chapter.