

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 405****[CMS–6025–F]****RIN 0938–AN42****Medicare Program; Limitation on Recoupment of Provider and Supplier Overpayments****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule implements a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) which prohibits recouping Medicare overpayments from a provider or supplier that seeks a reconsideration from a Qualified Independent Contractor (QIC). This provision changes how interest is to be paid to a provider or supplier whose overpayment is reversed at subsequent administrative or judicial levels of appeal. This final rule defines the overpayments to which the limitation applies, how the limitation works in concert with the appeals process, and the change in our obligation to pay interest to a provider or supplier whose appeal is successful at levels above the QIC.

DATES: *Effective Date:* These regulations are effective on November 16, 2009.

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SUPPLEMENTARY INFORMATION:**I. Background**

Prior to passage of the MMA, CMS could recoup overpayments regardless of whether a provider or supplier had appealed. Section 935(f)(2) of the MMA, codified at section 1892(f) of the Social Security Act, prohibits the recoupment of Medicare overpayments during a provider or supplier appeal to a Qualified Independent Contractor (QIC). CMS will also stop recoupment during the first level of appeal, the redetermination, if the provider or supplier files a timely request for appeal, as explained in detail within the text of this regulation. However, the contractor may initiate or resume recoupment, whether or not the provider or supplier subsequently appeals the QIC determination to the Administrative Law Judge (ALJ), the Medicare Appeals Council, or Federal court.

This final rule defines the overpayments to which the limitation on recoupment applies, how the limitation works in concert with the appeals process, and sets time limits for recouping overpayments, specifically providing 41 days for a provider or supplier to file the first level of appeal before the contractor can begin recoupment and providing the provider or supplier 60 days to appeal at the second level before the contractor can begin recoupment.

This final rule also changes how interest is to be paid to a provider or supplier whose overpayment is subsequently reversed at the ALJ, Medicare Appeals Council, or Federal court levels of appeal. Before the MMA was passed, CMS was liable for interest charges if it did not pay within 30 days of an underpayment determination. This final rule requires that if an overpayment determination is overturned in administrative or judicial appeals, above the QIC level of appeal, CMS is liable for interest on recouped overpayments that has accrued since the original determination. This final rule implements this new requirement, while leaving all other interest calculation regulations intact. Therefore, if a provider or supplier takes advantage of the limitation on recoupment, and ultimately loses on appeal, it will still be liable for all accrued interest.

A. Legislation

Section 935 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended Title XVIII of the Social Security Act (the Act) to add a new paragraph (f) to section 1893 of the Act, the Medicare Integrity Program. This new sub-section contains eight substantive provisions addressing the recovery of overpayments. This final rule implements the second of these provisions—the limitation on recoupment.

The statute requires us to change the way we recoup certain overpayments. It also changes how interest is to be paid to a provider or supplier whose overpayment determination is reversed at administrative or judicial levels of appeal above the QIC. We note that the changes to recoupment and interest work in tandem with Medicare fee-for-service claims appeal process. We refer readers to the September 22, 2006 proposed rule (71 FR 55406) or to the applicable regulations at 42 CFR 405.900 for a further discussion of the claims appeal process. The September 22, 2006 proposed rule includes a brief discussion of the appeals process and a detailed chart which sets forth the levels

of appeals as well as applicable time frames and amount in controversy requirements.

B. Appeals and Limitation on Recoupment

Recoupment is the recovery of a Medicare overpayment by reducing present or future Medicare payments and applying the amount withheld against the debt. Under our existing regulations, providers and suppliers can challenge an overpayment determination through both the rebuttal and appeals processes. The rebuttal process provides the debtor the opportunity to submit a statement and/or evidence stating why recoupment should not be initiated. The outcome of the rebuttal process could change how or if we recoup. Section 1893 of the Act as amended by Section 935 of the MMA and the provisions of this final rule do not alter the rebuttal process. The regulatory definition of “recoupment” is set forth at § 405.370. See § 405.374 for information on the rebuttal process.

An appeal is an examination of the validity of the overpayment determination. Before section 1893(f)(2) of the Act was enacted, if a provider or supplier elected to appeal, there was no effect on our ability to recover the debt. However, if the overpayment determination was reversed in whole or in part, at any stage of the administrative or judicial appeal process, appropriate adjustments would be made to the overpayment and the amount of interest assessed.

When section 1893(f)(2) of the Act was enacted, our recoupment process was changed. Section 1893 (f)(2) of the Act states:

In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any Medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered.

C. Assessment of Interest

In addition to changing the recoupment process, section 1893(f)(2) of the Act also has the effect of changing how we pay interest to a provider or supplier who is successful in having an overpayment determination fully or partially reversed at the latter stages of the appeal process.

Previously, we paid interest on underpayments solely in accordance with sections 1815(d) and 1833(j) of the Act. (See also, § 405.378.) An

underpayment would usually result when we had recovered, through recoupment or otherwise, an overpayment; the decision was fully or partially reversed at some point in the appeal process; and after appropriate adjustments, we owed the balance to the provider or supplier. Interest would accrue from the date of the "final determination" and was owed if the underpayment was not paid within 30 days. Following an appeal decision favorable to a provider or supplier, the Medicare contractor would effectuate the decision. If the decision created an underpayment, the contractor would issue a written determination of the amount Medicare owed as an underpayment. The written determination was considered a new final determination; interest would accrue from the date of the final determination and would be owed/ payable if the underpayment was not paid by the Medicare contractor within 30 days of the final determination of the underpayment.

The new interest provision found in section 1893(f)(2)(B) of the Act revises the way interest is to be paid to a provider or supplier whose overpayment determination is overturned in administrative or judicial appeals subsequent to the second level of appeal (the QIC reconsideration). Section 1893(f)(2)(B) of the Act states:

Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

Section 1893(f)(2)(B) of the Act does not specifically amend sections 1815(d) and 1833(j) of the Act. In addition, the MMA conference report does not reference these sections. The statute and the conference report are both silent on the relationship between paying or collecting interest: (1) Based on the final determination concept embodied in sections 1815(d) and 1833(j) of the Act; and (2) the concept of paying interest based on how long we held funds, ultimately determined through the latter stage of the appeal process to belong to the provider, as incorporated in section 1893(f)(2)(B) of the Act.

The statute does not change the obligation of the provider or supplier to pay interest if the overpayment determination is affirmed at any level of administrative or judicial appeal. In

accordance with sections 1815(d) and 1833(j) of the Act, interest continues to accrue from the date of the final determination as defined in § 405.378(c). Section 1893(f)(2)(B) of the Act explains that if an appeal of an overpayment is upheld before the QIC, "interest on the overpayment shall accrue on and after the date of the original notice of overpayment." For overpayments subject to the limitation on recoupment provision, the date of the final determination is the date of the original notice of overpayment (that is, the demand letter). Therefore, section 1893(f)(2)(B) of the Act is consistent with sections 1815(d) and 1833(j) of the Act and does not alter our ability to assess interest against the provider or supplier.

In addition, the statute does not change the obligation of Medicare to pay the provider or supplier interest if the overpayment determination is reversed at the first (redetermination) or second (reconsideration) level of the administrative appeal process and the appeal decision generates an underpayment. At these levels of appeal, interest would continue to be payable by Medicare if an underpayment is not paid to the provider or supplier within 30 days of the date of the final determination. The change in the method of paying interest resulting from section 1893(f)(2)(B) of the Act is applicable only where the reversal occurs at the Administrative Law Judge (ALJ) level or subsequent levels of administrative appeal or judicial review. At these higher levels of administrative appeal or judicial review, interest becomes payable by Medicare based on the period we recouped and retained the provider's or supplier's funds where the decision results in a full or partial reversal and Medicare previously recouped funds.

We determine the rate of interest in accordance with § 405.378 by comparing the private consumer rate with the current value of funds rate. Interest is assessed at the higher of these two rates that is in effect on the date of the final determination of the amount of the overpayment or underpayment. Since February 2001 to the present time, it has ranged from a low of 10.75 percent to a high of 14.125 percent. In accordance with § 411.24(m)(2), interest is calculated on Medicare Secondary Payer (MSP) debts in the same manner as for Medicare overpayments and underpayments. In addition, the same interest rate is used.

Interest accrues daily but is assessed and calculated in full 30 day periods. We charge simple rather than compound interest, and payments we

receive are applied first to accrued interest and then to principal. Interest we collect on overpayments and MSP recoveries goes to the general fund of the U.S. Treasury. The principal amount we recover is used to reimburse the applicable Medicare Trust Fund the Hospital Insurance (Part A) or the Supplementary Medical Insurance (Part B and now D) trust funds, which are special accounts in the U.S. Treasury. Interest we pay on Medicare underpayments comes from the applicable Medicare Trust Fund.

D. Suspension

We note that this new MMA provision does not affect how we recover overpayments from providers or suppliers that have been placed on payment suspension. Under § 405.371, an intermediary, a carrier, or CMS may suspend the payment of claims if there is reliable information that an overpayment, fraud, or willful misrepresentation exists or that payments to be made may not be correct. Once an overpayment amount is determined, suspended payments must first be applied to eliminate any overpayment as specified in § 405.372(e). We do not interpret section 1893(f)(2) of the Act as amending our authority to apply suspended payments toward reducing or eliminating an overpayment. Furthermore, we do not interpret section 1893(f) of the Act to require that suspended payments be released to a provider or supplier once an overpayment amount is determined. If the suspended payments are insufficient to fully eliminate any overpayment, and the provider or supplier meets the requirements of this final rule, the limitation on recoupment provision under section 1893(f)(2) of the Act will be applicable to any remaining balance still owed to CMS.

We also note that section 1893(f)(2) of the Act does not alter the process for providers or suppliers to appeal overpayment determinations that follow suspension actions. Providers and suppliers may continue to appeal the overpayment determination as they could before the enactment of the MMA.

II. Provisions of the Proposed Regulations and Response to Comments

In the September 22, 2006 **Federal Register** (71 FR 55404), we published the proposed rule entitled, "Limitation on Recoupment of Provider and Supplier Overpayments" and provided for a 60-day comment period. The rule proposed to implement a provision of the MMA that prohibited recouping Medicare overpayments when a reconsideration appeal is received from

a provider or supplier until a decision is rendered by a QIC. The provision changes how interest is to be paid to a provider or supplier whose overpayment is reversed at subsequent administrative or judicial levels of appeal. The proposed rule defined the overpayments to which the limitation applies, how the limitation works in concert with the appeals process, and the change in our obligation to pay interest to a provider or supplier whose appeal is successful at levels above the QIC.

We received a total of 11 timely comments from physicians, hospital associations, home health facilities, medical equipment providers, and other individuals and health care associations.

Brief summaries of each proposed provision, a summary of the public comments we received, and our responses to the comments are set forth below.

A. General Comments

Most of the comments received ranged from general comments that supported or opposed the proposed provisions, to very specific questions or comments regarding the proposed changes.

Comment: We received two comments that supported CMS's decision to halt recoupment during the period that the provider seeks a first level of appeal (redetermination) as stated in proposed § 405.379(d)(1).

Response: We appreciate the commenters recognizing that CMS has attempted to fairly implement the requirements of section 1893(f)(2) of the Act while still fulfilling its fiduciary responsibility to collect overpayments aggressively.

Comment: One commenter expressed concern that CMS's limitation on recoupment provisions afford greater protections to overpaid providers than to providers who are merely suspected to have overpayments and for whom payments are suspended while an overpayment is being determined.

Response: Section 1893(f)(2) of the Act prevents the Secretary from taking any "action * * * to recoup the overpayment". The disposition of suspended funds as explained in § 405.372(e) is not a "recoupment" as that term is defined in § 405.370. The statute does not broaden or alter CMS's definition of recoupment to also apply to the application of suspended funds. Because CMS is only limited by section 1893 (f)(2) of the Act from recouping Medicare payments, we are not restricted in our ability to apply

suspended funds to reduce or dispose of an overpayment.

B. Authority Citation for Subpart C of Part 405

Subpart C of part 405 implements several sections of the Act including sections authorizing the recovery of overpayments and assessment of interest. In the September 22, 2006 proposed rule, we proposed to revise the authority citation to explicitly add Section 1893 of the Act, amended by section 935 of the MMA, to add the limitation on recoupment as well as other provisions addressing the recovery of overpayments. We received no comments on this provision. Thus, in this final rule, we are adopting the authority citation provisions of the proposed rule without change.

C. Proposed Change to § 405.370 Definitions

Section § 405.370 defines key terms that apply to subpart C of part 405. In the September 22, 2006 proposed rule, we proposed to revise § 405.378 and add a new § 405.379. We added new definitions to § 405.370. We also proposed that selected terms used in § 405.378 and proposed § 405.379 be given the same meaning as in the appeals context.

Comment: Several commenters suggested that the definition of Medicare contractor be amended to include Recovery Audit Contractors (RACs).

Response: We agree with the commenter and have revised the definition of Medicare Contractor to include this change. We note that our intent was not to exclude RACs from being subject to the rule.

Accordingly, we are revising the definition of Medicare Contractor, and finalizing all other definitions in § 405.370 as proposed without change.

D. § 405.373 Proceeding for Offset or Recoupment

Section 405.373 establishes the general rules and procedures to be followed once CMS or a Medicare contractor determines that an offset or recoupment should be put into effect. Specifically, § 405.373(e) addresses the duration of a recoupment or offset that has been put into effect and identifies the three specific circumstances under which a recoupment or offset would stop. In the September 22, 2006 proposed rule, we proposed to revise the introductory text of paragraph (e) to explicitly refer to § 405.379, implementing the statutory limitation on recoupment, as a separate basis to

stop recoupments that have been put into effect.

We received no comments on these provisions. Accordingly, we are finalizing § 405.373 as proposed without modification.

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

Section 405.378 implements sections 1815(d) and 1833(j) of the Act which requires us to charge interest on overpayments and pay interest on underpayments if payment is not made within 30 days of the date of the "final determination". Under sections 1815(d) and 1833(j) of the Act, the date of the final determination dictates when interest begins to accrue and determines whether we pay interest on an underpayment or collect interest on an overpayment.

In paragraph (c), we define what constitutes a final determination both for overpayments and underpayments arising from a cost report determination as well as those that are claims based.

In paragraph (d), we establish the basis for the interest rate used for Medicare overpayments and underpayments as well as for other Medicare program activities, for example Medicare Secondary Payer recoveries (§ 411.24(m) which references § 405.378(d)).

In the September 22, 2006 proposed rule, we proposed to revise § 405.378 to specify how interest is assessed for the subset of overpayments subject to the limitation on recoupment under section 1893(f)(2) of the Act. In § 405.378, we proposed to clarify that if a provider or supplier overpayment determination is affirmed at any level of administrative or judicial appeal, interest owed by the provider or supplier would continue to accrue from the final determination. If the overpayment determination is reversed in favor of the provider or supplier, interest may be payable by Medicare to the provider or supplier under one of two different methodologies depending upon the appeal level at which the reversal occurs. If a full or partial reversal in favor of the provider or supplier occurs at the first (redetermination) or second (reconsideration) level of the administrative appeal process, interest may be payable by Medicare to the provider or supplier if the underpayment is not paid within 30 days of the final determination as that term is defined in the proposed revisions to § 405.378(c).

It is only where the reversal occurs at the ALJ level or Departmental Appeals Board's Appeals Council level of

administrative appeal or judicial review that interest becomes payable by Medicare based on the period that we recouped and retained the provider's or supplier's funds.

In the September 22, 2006 proposed rule, we proposed to amend § 405.378(a) by adding the reference to 1893(f)(2)(B) of the Act, which is one of the enumerated provisions of the Act that this regulatory section is designed to implement.

We also proposed to revise paragraph (b)(2), which states the basic rule that interest accrues from the date of final determination, to clarify there is a new exception to this rule by referencing paragraph (j) of this section.

In addition, we proposed to amend paragraph (c)(1)(ii) which lists what constitutes a final determination in cases where a Notice of Amount of Program Reimbursement (NPR) is not issued.

First, we proposed to remove the existing final determination definition based on certain Administrative Law Judge (ALJ) decisions under paragraph(c)(1)(ii)(C). The change in how interest is assessed under section 1893(f)(2) of the Act applies at the third level of appeal (ALJ) and subsequent administrative and judicial review levels. Therefore, we proposed to make these changes at paragraph (j).

Second, we proposed to add an additional definition for a final determination, at paragraph (c)(1)(ii)(C), arising from a full or partial reversal at the redetermination level of appeal. This change was designed to clarify that if an overpayment is reversed in whole or in part at the first level of appeal, the redetermination level, interest accrues from the date of the "final determination" and is owed by Medicare if the underpayment is not paid within 30 days. Following a redetermination decision favorable to a provider or supplier, the contractor must effectuate the decision and make a written determination of the amount Medicare owes. Interest accrues from the date of the written determination.

Finally, we proposed to add paragraph (c)(1)(ii)(D) as an additional type of final determination. This is a written determination arising from a full or partial reversal of an overpayment determination at the QIC reconsideration level (the second level of appeal). This addition was designed to clarify that if an overpayment determination is reversed in whole or in part at the QIC reconsideration, the final determination for purposes of assessing interest is the date of the written determination to the provider or supplier of the amount Medicare owes.

Interest accrues from the date of this written determination and is owed to the provider or supplier if the underpayment is not paid within 30 days.

These proposed changes to the final determination definitions are intended to work in conjunction with the limitation on recoupment requirements in § 405.379. Providers and suppliers can take advantage of the limitation on recoupment by not paying during the redetermination and reconsideration levels of appeal. However, interest will still continue to accrue during those periods. If a provider or supplier loses at either level of appeal, and they did not pay their overpayment during the appeal, they will owe both the overpayment amount and accrued interest.

We proposed to revise paragraph (c)(2) by adding the cross references to paragraphs (i) and (j) of this section which states the exceptions to assessing interest based on the date of final determination.

For purposes of clarity and to group the exceptions to the "final determination" rule in a logical sequence, we proposed to redesignate paragraph (h), respectively as paragraph (i) and paragraph (i) as paragraph (h). We note that the text of these redesignated paragraphs did not change.

In addition, we proposed to add a new paragraph (j) to establish the basis for paying interest to a provider or supplier whose overpayment determination is reversed in whole or in part at the third level of administrative appeal (ALJ) or above. This new interest provision is required by section 1893(f)(2)(B) of the Act which states, "[i]nsofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped." In paragraph (j), we explain how interest is assessed against the government at any administrative and judicial appeal level above the QIC reconsideration. This new method applies only to overpayments subject to the limitation on recoupment under § 405.379. It is predicated upon the recoupment and retention of funds by CMS or the Medicare contractor at the time the decision reversing the overpayment determination, in whole or in part, is rendered.

In paragraph (j)(1), we state that the rate of interest is the same rate that CMS charges on overpayments and pays on underpayments to providers, suppliers

and other health care entities. This rate, as specified in paragraph (d) of this section, is the higher of the private consumer rate or the current value of funds rate. We note that the interest rate established in paragraph (d) changes periodically.

In paragraph (j)(2), we describe the point in time where the applicable interest rate is fixed. This is the date the decision reversing the overpayment is issued by the ALJ, Medicare Appeals Council, Federal District Court or other Federal reviewing court.

In paragraph (j)(3), we explain how interest would be calculated. Interest will be paid on the total principal amount recouped. We will pay simple rather than compound interest, and will not pay interest on interest; this mirrors the manner in which we assess interest against providers. Monies we recoup and apply to interest will be refunded and not included in the "amount recouped" for purposes of calculating any interest due the provider. The periods of recoupment will be calculated in full 30-day periods; and interest will not be payable for any periods of less than 30 days in which we had possession of the recouped funds.

In calculating the period in which the amount was recouped, we will deduct days in which either or both the ALJ's or the Medicare Appeals Council's adjudication time frames are tolled due to specific actions by the appellant over which the government has no control. Our rules on the procedures and time frames to request an ALJ hearing provide that if the appellant fails to copy the other parties or files the request with an entity other than that specified in the QIC's reconsideration, the ALJ's 90 day adjudication deadline is tolled.

Similarly, our rules on the procedures and time frames to request a Medicare Appeals Council review provide that if the appellant fails to copy the other parties or files the request with an entity other than that specified in the notice of the ALJ's action, the Medicare Appeals Council's adjudication period to conduct a review is tolled. Therefore, in paragraph (j)(3)(iv) and (v), we state that in calculating how much interest we owe a provider or supplier, we account for these potential delays by deducting days attributable to actions by the provider or supplier which have the effect of extending the time in which we had possession of the recouped funds.

We state in paragraph (j)(4) that, in the cases of a partial reversal of an overpayment determination, we would allocate the funds recouped first to that portion of the overpayment

determination affirmed by the ALJ, Medicare Appeals Council, or any Federal court. If after this allocation excess recouped funds remain, interest would be paid to the provider or supplier on this amount in accordance with the other provisions specified in paragraph (j).

All comments and CMS's responses related to the proposed revisions of § 405.378 are discussed below:

Comment: Two commenters suggested that § 405.378(j) be revised to state that Medicare must pay interest from the date of recoupment regardless of whether the reversal occurs at the redetermination, reconsideration, or ALJ level.

Response: Section 1893 (f)(2)(B) of the Act clearly states that CMS must pay interest to a provider or supplier only when a reconsideration is "later reversed." Therefore, we are not authorized by statute to pay interest from the date of recoupment if a decision at the redetermination or reconsideration level of appeal reverses a prior determination or decision. The statute only requires the payment of interest back to the date of recoupment when a finding by an ALJ, or other higher administrative or judicial entity, reverses a QIC reconsideration decision. CMS only pays interest when specifically obligated by statute. We believe the commenter's suggestion is contrary to the plain meaning of the statute.

Comment: One commenter suggested that because interest charges continue to accrue against a provider or supplier even if they avail themselves of the limitation on recoupment, CMS will make itself whole by satisfying the overpayment through interest collections.

Response: CMS must forward to the (Department of Treasury) General Fund any interest collected. CMS neither retains, nor is made whole by interest collected on behalf of the Treasury.

Comment: One commenter stated that the proposed new definitions of when CMS pays interest on underpayments that result from a reversal, in whole or in part, at the redetermination level and at the reconsideration level (§ 405.378(c)(1)(ii)(C) and (c)(1)(ii)(D)), are not fair to providers or suppliers, and result in providers or suppliers giving interest-free loans to Medicare for the period of time between the decision and when Medicare effectuates the decision.

Response: Medicare's longstanding policy is that a final determination occurs when the determination sets forth a specific amount that is due. Further, as explained in § 405.378(e)(4),

interest to a provider or supplier does not begin to accrue until the date of the written determination notifying the provider or supplier of the amount of the underpayment. Although it is possible that a decision at the QIC level could include the precise amount that is owed as an underpayment, more often, the decision requires that the Medicare contractor compute the amount due to the provider. For example, if the QIC decision is a partial reversal of an overpayment where extrapolation was used to determine the overpayment, it typically must be recalculated to account for the revisions made to the sample claims upon which the extrapolated overpayment is based. Only after the recalculation of the overpayment is completed will the contractor become aware of any potential underpayment. A written determination on appeal that Medicare owes an underpayment but without specific information as to what the amount is owed, does not permit sufficient information to determine the payment amount and subsequent interest. Interest is paid when a specific amount is known and is not paid within 30 days. Similarly, providers have 30 days to repay an overpayment where the amount has been determined before interest is assessed.

In considering the comment, we decided to remove § 405.378(c)(1)(ii)(C) and (c)(1)(ii)(D). These two provisions included in our proposed rule explained when a final determination of an underpayment occurred during the first two levels of administrative appeal. However, we believe the language in § 405.378(c)(1)(ii)(B), which states that a written determination of an underpayment constitutes a final determination, adequately covers these two levels of appeal. Thus, we believe paragraphs (c)(1)(ii)(C) and (c)(1)(ii)(D) are unnecessary. After all levels of appeal, an underpayment will be determined when a sum certain is calculated and the provider or supplier is notified of the underpayment, regardless of whether a QIC or a contractor performs the recalculation.

Comment: One commenter stated that interest should be prorated for periods less than 30 days.

Response: CMS will continue to pay interest on underpayments it owes the provider or supplier, the same way it assesses interest on overpayments owed by the provider or supplier. Periods of less than 30 days are not counted. Only full 30 day periods are used to calculate interest. This is based on § 405.378(b)(2) where interest accrues and is paid for each full 30 day period that payment is delayed.

Comment: Two commenters asked CMS to reconsider the proposal to deduct from the interest owed to the provider those days that are tolled during an ALJ or Appeals Council adjudication period.

Response: The appeals regulations in § 405.1014 and § 405.1106 provide extensions (or tolling) of the adjudication timeframe for issuance of ALJ decisions and Medicare Appeals Council review decisions when certain specific actions are taken by an appellant that are outside the government's control, (for example, the appellant fails to copy the other parties on their request for an ALJ hearing). We believe that our proposal to deduct the days that are associated with an appellant's actions aligns itself with the language in the appeals regulations. CMS should not be required to pay interest on days that the appellant is in control of, or is perfecting an appeal request, or takes action that delays the administrative proceedings.

Accordingly, we are finalizing § 405.378 as proposed with modifications, as noted above.

F. § 405.379 Limitation on Recoupment of Provider and Supplier Overpayments.

In the September 22, 2006 proposed rule, we proposed to add a new section § 405.379 to subpart C of Part 405 to implement the statutory limitation on recoupment under section 1893(f)(2) of the Act.

Specifically, in proposed paragraph (a) we explained that 1893(f)(2)(B) of the Act is the statutory basis for this section. In addition, we stated that the basis and purpose of this section is to impose a limit on our recoupment of Medicare overpayments, if a provider or supplier appeals until a decision by a QIC is made.

In paragraph (b), we delineated those types of overpayments that are expressly subject to the recoupment limitation: (1) those appealed by the provider or supplier under the Medicare claims appeal process; (2) post-pay denial of claims for benefits under Medicare Part A and Part B for which a demand for payment has been made; and (3) Medicare Secondary Payer (MSP) recoveries where the provider or supplier received a duplicate primary payment and MSP recoveries 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.

Section 935(b) of the MMA specified that section 1893(f)(2) of the Act shall apply to "actions" taken after the date of enactment of the MMA; that is actions taken after December 8, 2003.

For these purposes, we defined these actions to be the date the contractor could have instituted recoupment action based on Part A debts determined on or after November 24, 2003, Part B debts determined on or after October 29, 2003, and a small group of MSP debts determined on or after October 10, 2003.

In paragraph (b), we also provided the categories of overpayments to which the limitation does not apply, although this is not an exhaustive list of exclusions. The limitation would not apply to all MSP recoveries other than provider/supplier MSP duplicate primary payment recoveries or MSP recoveries attributable to the provider's or supplier's failure to file a proper claim. It would not apply to beneficiary overpayments nor overpayments that arise from a cost report determination and are appealed under the provider reimbursement process.

In paragraph (c), we specified how two key actions that trigger the limitation on recoupment are to be construed. A provider must act decidedly to stop recoupment. Recoupment of an overpayment once initiated will be stopped at the first two levels of the appeals process (the redetermination and the reconsideration) upon receipt of a timely and valid appeal request applicable to that level. The provider or supplier does not have to take any affirmative action to invoke the limitation on recoupment beyond the act of appealing. What constitutes a valid and timely request for a redetermination and, subsequently what constitutes a valid and timely request for a reconsideration is already described in established Medicare appeal regulations and implementing policies. (See 42 CFR part 405 subpart I).

In paragraph (d), we proposed the general framework for implementing the limitation on recoupment. Once an overpayment is determined and the substantive and procedural requirements to afford the provider or supplier an opportunity for rebuttal under § 405.374 and § 405.375 are satisfied, recoupment can proceed unless and until a valid request for a redetermination is received. This means we can recoup during the period when a provider's or supplier's right to request a redetermination has not expired. This places the obligation on the provider or supplier who wishes to capitalize on the benefit afforded by the recoupment limitation to request a redetermination.

Under the Benefits Improvement and Protection Act of 2000, the Medicare contractor is required to make a

redetermination decision within 60 calendar days of the date the contractor receives a timely filed request for a redetermination. We proposed in paragraph (d)(2) that if the redetermination is an affirmation in whole or in part, we can proceed to recoup any outstanding principal and interest 30 days after notice unless a valid request for a reconsideration is received in the interim.

In paragraph (d)(3), we specified that the Medicare contractor shall cease recoupment upon receipt of a timely and valid request for a reconsideration. If recoupment has not gone into effect, the contractor shall not initiate it. The contractor may initiate or resume recoupment upon final action by the QIC in accordance with paragraph (f) which is explained in detail below.

The general rule we proposed in paragraphs (d)(4) and (d)(5) states that, unless the reconsideration results in a full reversal of the overpayment determination, recoupment of outstanding principal and interest may be initiated or resumed upon final action by the QIC whether or not the provider or supplier appeals to the ALJ, the Medicare Appeals Council, or Federal court. If the provider or supplier subsequently appeals, the contractor may continue recouping outstanding overpayments in accordance with § 405.373(e).

In paragraph (d)(6), we clarified that each overpayment determination and its appeal status is separate and distinct from other debts owed by the same provider or supplier. Therefore, we make explicit that if an overpayment determination is appealed and recoupment stopped, this would not preclude the Medicare contractor from recouping other overpayments owed by the provider or supplier.

In paragraph (d)(7), we stated that amounts properly recouped before the imposition of the recoupment limitation, at either or both the first and second levels of appeal, may be retained until and unless there is an administrative or judicial reversal of the overpayment determination.

In paragraph (d)(8), we stated that if an overpayment determination is reversed through the administrative or judicial process, appropriate adjustments in the debt and the amount of interest charged would be made to give effect to these decisions.

In paragraph (d)(9), we made explicit that interest is payable on overpayments, subject to the recoupment limitation, in accordance with the provisions of § 405.378.

In paragraph (e), we stated the specific rules for initiating or resuming

recoupment after the redetermination decision. The necessary conditions are that the debt (remaining unpaid principal balance and interest) has not been liquidated and the substantive and procedural rebuttal requirements have been satisfied. We proposed that recoupment can resume: (1) Immediately upon receipt of a request to withdraw the redetermination request; (2) on the 30th calendar day after the date of the notice of redetermination affirming the overpayment determination in whole; or (3) on the 30th calendar day after a written notice to the provider or supplier of the revised overpayment amount if the redetermination results in an affirmation in part. We proposed in paragraph (e)(2), that recoupment would be stopped again upon receipt of a timely and valid request for a reconsideration by the QIC.

In paragraph (f), we set forth the specific rules for initiating or resuming recoupment after final action by the QIC. It also defines what constitutes final action by a QIC for purposes of this section. As is the case when recoupment is resumed after the redetermination decision, the conditions necessary for resumption are that the debt (remaining unpaid principal balance and interest) has not been liquidated and the substantive and procedural rebuttal requirements have been satisfied.

Under the statute, once a provider or supplier has sought a reconsideration by the QIC, we may not take any action to recoup the overpayment until the date the decision on the reconsideration has been rendered. We believe it is consistent with this provision to interpret "the date the decision on the reconsideration is rendered" as the date on which the QIC issues its final decision, dismissal order, or notice with respect to escalation.

There are three possible actions that a QIC may take with respect to a request for reconsideration. First, it may complete its review and issue a reconsideration. Second, in appropriate circumstances, it may dismiss the request for reconsideration. Third, if the QIC is unable to complete its reconsideration within the mandated 60 day time frame, it may issue a notice to the parties that it will not be able to complete its reconsideration in the allotted time and advise them of their right to escalate their appeal to the ALJ level. The parties may then notify the QIC of their intent to escalate the appeal. Following the receipt of this notice, the QIC must either issue its reconsideration within 5 days or issue a notice acknowledging the escalation

request and forward the case file to the ALJ hearing office.

We proposed that the earliest to occur of these three actions (a reconsideration, a dismissal, or the written notification to the parties that the reconsideration has been escalated) or the receipt of a withdrawal request from the provider or supplier would constitute the final QIC action that would permit the initiation, or resumption, of the recoupment of an overpayment. The provider or supplier who elects to escalate the appeal from the QIC to the ALJ would thereby lose the benefit of the limitation on recoupment (recoupment could begin). However, we do not view this as a disadvantage to the provider or supplier who retains the ability to seek escalation or not to seek escalation. We also clarified that where the final action is the notice of the reconsideration, in order to institute or resume recoupment, the reconsideration decision must affirm the overpayment determination in whole or in part.

In paragraph (g), we addressed a series of specific rules and situations on how recouped funds are to be applied. Funds recouped before receipt of a timely and valid redetermination request may be retained and applied first to accrued interest and then to the principal balance. If the overpayment in question is reversed at the first level of appeal, consistent with current policies, the amount held may be applied to any other debt owed by the provider or supplier; any excess would then be released to the provider or supplier.

In the case of a partial reversal at the redetermination level in which the decision reduces the debt below the amount already recouped, the same policies would be followed with respect to the application of the recouped funds. In the case of an affirmation where the provider or supplier appeals to the next level, the Medicare contractor would retain the monies and apply them first to interest and then to the principal balance pending final action by the QIC on the reconsideration request.

If funds are properly recouped between a redetermination decision and a provider's subsequent request for a reconsideration, these would be retained and applied first to interest, then to principal pending final action by the QIC. If the final QIC action is a dismissal, receipt of a withdrawal, notice of escalation, or a reconsideration decision affirming the overpayment in whole, funds recouped are applied to interest, then to principal; recoupment may be resumed as necessary to liquidate the debt. If the QIC reconsideration decision is a full

reversal, the amount recouped may be applied to any other debt (including interest) owed by the provider or supplier before any excess is released. If the reconsideration decision is a partial reversal and reduces the debt below the amount already recouped, the same policies would be followed with respect to the application of the recouped funds.

In paragraph (h), we specified how we would insulate a provider or supplier, invoking the limitation on recoupment under this section, from the operation of § 401.607(c)(2)(iv). This latter rule provides that missing one payment under a 6-month extended repayment plan granted under the authority of § 401.607(c)(2) constitutes a default allowing CMS to accelerate the debt.

All comments and CMS's responses related to § 405.379 are discussed below:

Comment: Two commenters stated that in the proposed rule CMS explained that it would not recoup until after the requirement to afford the provider or supplier an opportunity for rebuttal was satisfied. In addition, the commenters asked if the rebuttal process conflicts with the proposed provisions.

Response: The rebuttal process is a separate and independent right that is not affected by this regulation, and occurs independently of the appeals process set forth in part 405 subpart I. The statement in the proposed regulation regarding the rebuttal process was simply an acknowledgement that this process remains available to providers and suppliers. Sections 405.373 through 405.375 explain the process by which CMS gives notice of an overpayment and offers an opportunity for rebuttal before it takes an action to offset or recoup that overpayment. The provider may submit a rebuttal statement within 15 days of the notice. The Medicare contractor has 15 days to review the statement and determine whether to proceed with the recoupment or not to proceed, based on the rebuttal statement. In contrast, the limitation on recoupment provision does not afford the contractor any discretion in proceeding or stopping recoupment of an overpayment. If a valid request for a first or second level appeal is filed, the contractor must stop recoupment. As a practical matter, providers who want to ensure that CMS stops recoupment will avail themselves of the limitation on recoupment process through a timely and valid appeal rather than the rebuttal process.

Comment: Several commenters recommended that CMS provide the full 120-day filing period for a

redetermination and the 180-day period for a reconsideration before starting recoupment of the overpayment. The commenters indicated that the proposed rule forces providers to choose either to initiate a timely appeal to stop recoupment, or take full advantage of the timeframe for filing an appeal. In addition, the commenters stated that recouping before the filing periods have concluded was not in compliance with the statute.

Response: The comment that recoupment should be delayed 120 days after the receipt of an overpayment determination or 180 days after the notice of a redetermination is inconsistent with the applicable statute. In order to trigger the statutory limitation on recoupment, the provider must seek a reconsideration. The statute is clear that recoupment is either stopped, or may not begin, when a valid request for a reconsideration is filed. However, the statute is silent with regard to actions CMS may take after an initial demand is issued and before a request for reconsideration is filed. CMS has a fiduciary responsibility to timely and aggressively collect Medicare debt or refer the debt to Treasury for collection as mandated by the Debt Collection Improvement Act. Unless a provider or supplier purposely avails themselves of the limitation on recoupment, CMS has a statutory obligation to collect these outstanding debts. Based on the statutory language CMS could recoup during the period the provider is actively pursuing a first level of appeal (redetermination). This approach would reduce the complexity of implementing this new statutory provision. Also, it would shorten the period of deferred recoupment under the Act, thereby minimizing risk to the Medicare Trust Fund. However, as we noted earlier, this approach would result in many instances where CMS would have recouped the overpayment before the provider could request a reconsideration and thereby invoke the limitation on recoupment. We suggested in our September 2006 proposed rule that this view, while permissible, would unfairly impact many providers and suppliers. Using our discretionary rulemaking authority, CMS is also limiting recoupment when the provider requests a redetermination (that is, the first level of appeal). Based on this comment, CMS is revising § 405.379(a) to make clear that we are implementing the statutory requirement to limit recoupment during reconsideration, as well as limiting recoupment during redetermination, the first level of appeal.

In both cases, the provider or supplier must take some decided affirmative action, (that is, requesting a redetermination or a reconsideration). Moreover, to wait until the expiration of the appeals filing periods would adversely impact providers and suppliers who do not wish to appeal, because they would be subject to several months of interest. To avoid this, these providers and suppliers would have to take some affirmative action to indicate that they do not want to appeal which unfairly places a burden on these providers and suppliers who want to pay their overpayments and do not want to appeal.

Therefore, CMS has determined that the timeframes established for recoupment are both reasonable for allowing providers sufficient time to initiate a timely appeal and are also consistent with our fiduciary responsibility for collecting Medicare debt. Based on the foregoing discussion, CMS is in compliance with the statute. We are not adopting the commenters' suggestion.

Comment: One commenter suggested that if CMS does not halt recoupment until the first and second level appeals periods expire, CMS should require a provider or supplier to inform the contractor of its intent to initiate an appeal. In addition, the commenter indicated that providers expressing their intent to appeal would not be subject to recoupment.

Response: We believe the language of the statute that the provider must "seek" a reconsideration clearly intends for a process that actively engages both the provider or supplier and CMS. An intent to file has no time limits for a provider or supplier and has the effect of staying any collections indefinitely. Further, simply signaling an intent to file has no binding effect on a party, and does not necessarily mean that a provider or supplier will ultimately seek any appeal. Thus, we are not adopting the commenter's suggestion.

Comment: One commenter suggested that CMS should ensure that language in the overpayment notices clearly advise the provider or supplier that if it files a request for a redetermination by a specified date that recoupment would be stayed and that these notices should also specify the time period in which recoupment would be stayed. Additionally, language in the notices should state that interest continues to accrue from the date of the original overpayment determination.

Response: We agree with the commenter that language regarding when recoupment starts and stops and that interest continues to accrue from

the date of the initial overpayment determination should be included in the overpayment determination letters. However, we view those procedures as part of the specific manual instructions to be issued to Medicare contractors. Manual instructions contain model letters and instructions to Medicare contractors on the preparation and content of demand letters. Thus, we do not believe it is necessary to revise the rule to include the commenter's suggestion.

Comment: Two commenters stated that the limitation of recoupment should apply to those Part B debts determined on or after October 29, 2003 and Part A debts determined on or after November 29, 2003. The commenters further explained that this means that CMS could begin recoupment on the 16th day or the 41st day after the notice of overpayment is issued and before a redetermination is filed depending on whether the notice came from the Medicare intermediary or the Medicare carrier. The commenter expressed that this is disparate treatment and asked CMS to explain the rationale for the policy.

Response: Medicare contractors' internal shared systems largely determined when those contractors instituted recoupment. Recoupment began approximately 16 days after the notice of overpayment, if the notice was issued by a Medicare intermediary, and 41 days after the notice of overpayment if the notice was issued by a Medicare carrier unless in both cases, the contractor received information from the provider about how it intended to repay the overpayment.

The limitation on recoupment provision required us to consider more consistent system rules for when recoupment could begin or resume. For consistent application of the limitation on recoupment and before a request for a redetermination is received, we modified our Part A systems to be consistent with our Part B systems and both will begin recoupment at day 41 following the notice of overpayment for those overpayments subject to the limitation on recoupment. This aligns itself with interest regulations at § 405.378, that states interest is not due if the debt is liquidated within 30 days. If a provider or supplier pays the overpayment or requests a redetermination by the 30th day following the notice of overpayment, Medicare contractors have an additional 10 days to ensure posting of payments or receipt of a valid request for a redetermination. Medicare overpayment demand letters will include clear language about when recoupment can

begin. We are also amending the regulation at § 405.379(d)(1) to reflect the 41 day system modification.

Comment: Two commenters stated that providers who fail to introduce all relevant evidence before the QIC are precluded from presenting new evidence to an ALJ, absent good cause. Thus, an appellant may need more than 30 days to prepare a request for reconsideration that contains all relevant evidence.

Response: The requirement in § 405.966 for the early presentation of evidence by providers and suppliers is based on the statutory requirement contained in section 1869(b)(3) of the Act, as added by section 933(a) of the MMA, which states that a provider or supplier may not, in any subsequent level of appeal, introduce evidence that was not presented at the reconsideration conducted by the QIC, unless there is good cause that precluded the introduction of that evidence at or before the reconsideration. While it is in the interest of both the Medicare provider and supplier community and CMS that appellants have the opportunity to submit a complete appeal request with all relevant evidence, we believe it is necessary to strike a balance between the need to timely recoup Medicare overpayments and the need to give providers and suppliers a reasonable time to prepare an appeal.

Therefore, after carefully considering all comments received, we have decided to extend the period before contractors may initiate recoupment following a redetermination to the 60th calendar day rather than the 30th calendar day. Providers or suppliers may take the full 180 days to appeal. However, to avoid recoupment starting or resuming following a redetermination, a valid request for reconsideration must be filed with the appropriate QIC by the 60th day following the date of the redetermination. This change is reflected at § 405.379(e)(1)(ii) and (e)(1)(iii).

Comment: One commenter indicated that there is no provision to notify the provider or supplier that recoupment has stopped once the provider or supplier submits a request for reconsideration to the QIC. The commenter recommended that the QIC issue to the provider or supplier a written notification that recoupment efforts have ceased once they file a request for reconsideration to the QIC.

Response: As part of the QICs' current standard operating procedures, QICs send an acknowledgement notice within 14 days of receipt of a request for reconsideration to the provider or

supplier. However, the Medicare contractor, not the QIC, is responsible for all overpayment recoupment activities, including the cessation of recoupments. The provider or supplier is notified by the Medicare contractor via a payment remittance advice that claims are continuing to be paid and are not being recouped or offset. We will consider whether any additional notice is necessary and, if so, we will include additional guidance in our manual instructions rather than through a regulatory issuance.

Comment: One commenter stated that recoupment should cease upon a request for reconsideration and should not be initiated or resumed until after an ALJ or judicial decision was rendered.

Response: When a valid request for a reconsideration is received, recoupment ceases. Section 1893(f)(2) of the Act only requires CMS to stop recoupment when a valid request for reconsideration is received. It does not limit CMS' authority to resume recoupment following the reconsideration decision issued by the QIC. Thus, as stated in § 405.379(d)(4) and (d)(5), recoupment can resume following a decision by the QIC, whether or not the QIC decision is further appealed. Therefore, we are not adopting the commenter's suggestion, as we believe the suggestion is contrary to section 1893(f)(2) of the Act. However, we are making technical changes to § 405.379(d), (f), and (g) of this section to remove the word "final" preceding "action." We believe that use of the word "final" in these provisions is confusing because "final action" could be incorrectly construed as meaning a final administrative action of the Secretary which can be appealed directly to Federal district court. The intent of this regulatory provision is to explain the types of actions by the QIC that are binding on the parties and would enable recoupment to be initiated or resumed. As was stated in the proposed rule and this final rule, these actions are a decision, dismissal order, or notice that it cannot complete its reconsideration in a timely manner. Because the underlying QIC actions that will allow CMS to initiate or resume recoupment have remained unchanged, we are making only a non-substantive, technical change to clarify the ambiguity discussed above by deleting the word "final."

We also note one further technical change we are making to § 405.379(c). In this paragraph, we revised incorrect cross-references to § 405.940 and § 405.958, and cross references to § 405.974 through § 405.978. Specifically, we revised the regulatory text of (c)(1) to refer to § 405.940

through § 405.958 and we revised the regulatory text of (c)(2) to refer to § 405.960 through § 405.978.

Comment: One commenter suggested that a provider's choice to escalate the appeal to the ALJ because of a delay at the QIC should toll recoupment.

Response: Notice by the QIC that it is unable to meet the mandated response timeframe for issuing a decision immediately gives the provider or supplier control to request an ALJ appeal. Practically, this result is no different than a decision issued by the QIC that affirms the prior decision and the provider or supplier requests an appeal. In both instances the appeal has passed out of the reconsideration level and the statutory requirement to limit recoupment no longer applies. We note that we are not adopting the commenter's suggestion.

Comment: One commenter stated that CMS has not addressed how extended repayment plans work in conjunction with the limitation on recoupment. The commenter stated that a provider might want to repay the overpayment by seeking an extended repayment plan at some point in the appeals process. For example, the provider might not have a favorable decision at the first level of appeal and chooses not to appeal to the second level. Also, the commenter recommended that CMS revise the rule to include language that recoupment may not occur for 30 days after the redetermination and/or reconsideration to give the provider time to request and CMS to review and approve an extended repayment plan.

Response: In paragraph (h) of § 405.379, we state that a provider or supplier who timely files a redetermination of an overpayment but such overpayment is under an extended repayment plan, a missed payment under the plan does not put the provider in default of the extended repayment plan. This permits the provider or supplier to invoke the limitation on recoupment provisions to stop recoupment when a valid request for redetermination is filed. We are revising paragraph (h) of § 405.379 to permit the provider or supplier to similarly invoke the limitation on recoupment if a timely and valid request for reconsideration is received. Additionally, in this final rule, we do not prohibit the provider or supplier from requesting a repayment plan at any time or at any stage of an appeal. Payments made by a provider or supplier who requested to repay in installments under an extended repayment plan are not recoupments for purposes of this rule. If a provider or supplier does not make timely payments

under its schedule, the provider or supplier would be placed on recoupment but can invoke the benefit of the limitation as stated above.

Providers or suppliers who wish to make repayment arrangements following a redetermination can do so during the 60 days the provider or supplier is also deciding whether to appeal to a reconsideration. Providers or suppliers who wish to make repayment arrangements following a reconsideration have the opportunity to do that during the rebuttal period required under § 405.374.

We note that we have revised paragraph (h) of § 405.379 for clarity. Yet these revisions do not make substantive changes to the policy. Further we corrected an incorrect cross reference to § 401.607(c)(2)(iv). Specifically we revised the regulations text to refer to § 401.607(c)(2)(v).

Comment: One commenter suggested that CMS give the provider the option of repaying the overpayment immediately, even if the provider appeals the overpayment determination. The commenter also stated that paying the debt immediately allows the provider to exercise their appeal rights without incurring substantial interest charges. The commenter also stated that the statute does not preclude the provider from voluntarily returning funds during the administrative appeals process.

Response: We appreciate the observations and the suggestion submitted by the commenter. Currently, providers or suppliers have several options at the time of the notice of overpayment. For example, they may pay the overpayment and not pursue an appeal, pay the overpayment and proceed with an appeal, or not pay the overpayment and proceed with a timely appeal. Providers or suppliers who choose to pay immediately, as the commenter suggests, avoid paying interest. Also, as the commenter suggested, providers or suppliers can voluntarily repay any time during the appeal, thereby limiting their interest exposure. Because payments made as a lump sum or through an extended repayment plan are not recoupments subject to the limitation, no modifications are necessary.

Accordingly, we are finalizing § 405.379 with modifications as noted above.

III. Provisions of the Final Rule

- In this final rule, we are adopting the provisions as set forth in the September 22, 2006 proposed rule with the following revisions:

- In § 405.370(b), we revised the definition of Medicare contractor to include a recovery audit contractor.

- In § 405.378(c), we removed paragraphs (c)(1)(ii)(C) and (c)(1)(ii)(D) regarding the definition of a final determination.

- In § 405.379(a) we made revisions to make clear that we are implementing the statutory requirement to limit recoupment during reconsideration, as well as limiting recoupment during redetermination, and the first level of appeal.

- In § 405.379(c) we revised incorrect cross-references to § 405.940 and § 405.958, and cross references to § 405.974 through § 405.978. Specifically, we revised the regulatory text of (c)(1) to refer to § 405.940 through § 405.958 and we revised the regulatory text of (c)(2) to refer to § 405.960 through § 405.978.

- In § 405.379(d), we added language to paragraph (d)(1) to provide that recoupment may begin no earlier than 41 days following the date of the initial notice of overpayment.

- In § 405.379(d), we made a technical change to paragraph (d)(4) by removing the word “final” to clarify that actions of a QIC are not necessarily considered final administrative actions of the Secretary which can be appealed directly to Federal district court.

- In § 405.379(e), we revised paragraphs (e)(1)(ii) and (e)(1)(iii) to extend the timeframe for limiting recoupment before reconsideration is filed from 30 calendar days to 60 calendar days.

- In § 405.379(f) and (g), we made technical changes. Specifically, we revised the heading of paragraph (f) by removing the word “final”. In paragraphs (f)(1) and (2), and (g)(1) and (2), we removed the word “final”. We made these technical changes to clarify that actions of a QIC are not necessarily considered final actions of the Secretary which can be directly appealed to Federal district court.

- In § 405.379(h), we added language that permits the provider or supplier who might otherwise be found to be in default on their extended repayment schedule, but submits a valid and timely reconsideration not be deemed in default. We also revised paragraph (h) for clarity. These revisions do not make substantive changes to the policy. Further we corrected an incorrect cross reference to § 401.607(c)(2)(iv). Specifically we revised the regulatory text to refer to § 401.607(c)(2)(v).

IV. Collection of Information Requirements

This document does contain information collection requirements; however, the Paperwork Reduction Act of 1995 exempts the information collection activities referenced in this Final Rule. In particular, 5 CFR 1320.4 excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment. See also, 44 USC 3518(c).

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We do not expect this final rule to have a substantial financial impact on beneficiaries, providers, or suppliers. Additionally, we anticipate that Federal costs to implement this final rule will be approximately \$1 to \$10 million per year in additional interest payments, which is well under the threshold of \$100 million in any 1 year.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small businesses or other small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. The great majority of hospitals and most other providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than 7 million to 34.5 million in any 1

year). For purposes of the RFA, all providers and suppliers affected by this regulation are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act. We are uncertain how many small entities would be affected by this final rule as this would depend in part upon voluntary actions on the part of the provider or supplier. The purpose of this rule is to limit our ability to recoup against providers or suppliers who appeal an overpayment determination. In order to impact a provider or supplier, the provider or supplier must have received an erroneous payment; an overpayment must be determined and demanded; the provider or supplier must elect to appeal; and the provider or supplier may not satisfy the overpayment by making either a lump sum payment or requesting to repay the debt in installments. The only possible adverse impact upon a provider or supplier is that by deferring repayment of the overpayment until final action by the QIC, the provider would owe additional interest. However, the provider or supplier can avoid the additional interest exposure by electing to satisfy the debt by a lump sum payment or an installment payment while still pursuing the appeal. In addition, should the overpayment determination be reversed at a level above the QIC, the provider or supplier potentially will receive additional interest beyond what CMS would be obligated to pay under current regulations. Therefore, we expect the impact of this final rule to be positive although the extent to which it would benefit any one provider or supplier would depend upon specific facts and circumstances and voluntary choices made by that provider or supplier. The impact on small rural hospitals is expected to be similarly positive but unpredictable. Therefore, we are certifying that this final rule will not have a significant impact on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is \$133 million. This rule will not have this effect on State, local, or tribal governments, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This final rule will not have a substantial effect on State or local governments.

A comment and the CMS response to the impact analysis section are discussed below:

Comment: One commenter states that CMS should have performed an impact analysis because the commenter believes that the CMS proposal to recoup before the 120 day time period for filing a request for redetermination has expired may not afford protections from recoupment and may have an impact on small business. Additionally, the commenter believes CMS can determine negative impact by looking at overpayment data.

Response: As previously stated CMS plans to adopt a process that will give providers and suppliers an opportunity to stop recoupment if they act decidedly by submitting a request for redetermination within 30 days of the initial notice of overpayment. CMS will not begin recoupment until the 41st day allowing Medicare contractors time to act on information it receives from the provider. Also, after reviewing public comments concerning the timeframe to limit recoupment before reconsideration is filed; CMS is expanding the 30 day time limit to 60 days. We believe that these timeframes afford providers or suppliers ample protections to stop recoupment. Thus, we are not adopting the commenter's suggestion.

B. Conclusion

For these reasons, we did not prepare analyses for either the RFA or section 1102(b) of the Act because we have determined that this final rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation

was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure; Health facilities; Health professions; Kidney diseases; Medical devices; Medicare; Reporting and recordkeeping requirements; Rural areas; X-rays.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

■ 1. The authority citation for subpart C is revised to read as follows:

Authority: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, 1892 and 1893 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395cc, 1395gg, 1395hh, 1395pp, 1395ccc and 1395ddd) and 31 U.S.C. 3711.

■ 2. Section 405.370 is amended by designating the existing text as paragraph (a), and adding a new paragraph (b) to read as follows:

§ 405.370 Definitions.

* * * * *

(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) 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.

■ 3. In § 405.373, paragraph (e) introductory text is revised to read as follows:

§ 405.373 Proceeding for offset or recoupment.

* * * * *

(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:

* * * * *

■ 4. Section 405.378 is amended by—

■ A. Revising paragraph (a);

■ B. Revising paragraph (b)(2);

■ C. Republishing paragraph (c)(1) introductory text;

■ D. Revising paragraph (c)(1)(ii);

■ E. Revising paragraph (c)(2);

■ F. Redesignating paragraphs (h) and (i) as paragraphs (i) and (h) respectively;

■ G. Adding paragraph (j).

§ 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) * * *

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

* * * * *

(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.

* * * * *

(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.

* * * * *

(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.

■ 5. Section 405.379 is added to read as follows:

§ 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 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 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.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 29, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 17, 2009.

Kathleen Sebelius,

Secretary.

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