items or services furnished during a period of denial or revocation may be resubmitted to CMS within 1 year after the date of reinstatement or reversal.

§ 405.818 Deadline for processing provider enrollment initial determinations.

Contractors approve or deny complete provider or supplier enrollment applications to approval or denial within the following timeframes:

(a) *Initial enrollments.* Contractors process new enrollment applications within 180 days of receipt.

(b) *Revalidation of existing enrollments.* Contractors process revalidations within 180 days of receipt.

(c) *Change-of-information and reassignment of payment request.* Contractors process change-of-information and reassignment of payment requests within 90 days of receipt.

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the following provisions of the Act:

(1) Section 1869(a) through (e) and (g) of the Act.

(2) Section 1862(b)(2)(B)(viii) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under Part A or Part B, including an initial determination made by a quality improvement organization under section 1154(a)(2) of the Act or by an entity under contract with the Secretary (other than a contract under section 1852 of the Act) to administer provisions of titles XVIII or XI of the Act.

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015]

§ 405.902 Definitions.

For the purposes of this subpart, the term—

ALJ means an Administrative Law Judge of the Department of Health and Human Services.

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.

Applicable plan means liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan.

Appointed representative means an individual appointed by a party to represent the party in a Medicare claim or claim appeal.

Assignee means:

(1) A supplier that furnishes items or services to a beneficiary and has accepted a valid assignment of a claim or

(2) A provider or supplier that furnishes items or services to a beneficiary, who is not already a party, and has accepted a valid assignment of the right to appeal a claim executed by the beneficiary.

Assignment of a claim means the transfer by a beneficiary of his or her claim for payment to the supplier in return for the latter's promise not to charge more for his or her services than what the carrier finds to be the Medicare-approved amount, as provided in §§ 424.55 and 424.56 of this chapter.

Assignment of appeal rights means the transfer by a beneficiary of his or her right to appeal under this subpart to a provider or supplier who is not already a party, as provided in section 1869(b)(1)(C) of the Act.

Assignor means a beneficiary whose provider of services or supplier has

taken assignment of a claim or an appeal of a claim.

Authorized representative means an individual authorized under State or other applicable law to act on behalf of a beneficiary or other party involved in the appeal. The authorized representative will have all of the rights and responsibilities of a beneficiary or party, as applicable, throughout the appeals process.

Beneficiary means an individual who is enrolled to receive benefits under Medicare Part A or Part B.

Carrier means an organization that has entered into a contract with the Secretary in accordance to section 1842 of the Act and is authorized to make determinations for Part B of title XVIII of the Act.

Clean claim means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under title XVIII within the time periods specified in sections 1816(c) and 1842(c) of the Act.

Contractor means an entity that contracts with the Federal government to review and/or adjudicate claims, determinations and/or decisions.

Family member means for purposes of the QIC reconsideration panel under § 405.968 the following persons as they relate to the physician or healthcare provider.

(1) The spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance);

(2) Children (including stepchildren and legally adopted children);

(3) Grandchildren;

(4) Parents; and

(5) Grandparents.

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.

MAC stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

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.

Provider means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

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.

Quality Improvement Organization (QIO) means an entity that contracts with the Secretary in accordance with sections 1152 and 1153 of the Act and 42 CFR subchapter F, to perform the functions described in section 1154 of the Act and 42 CFR subchapter F, including expedited determinations as described in § 405.1200 through § 405.1208.

Reliable evidence means evidence that is relevant, credible, and material.

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.

Similar fault means to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim as defined in part 411 of this chapter.

Supplier means, unless the context otherwise requires, a physician or other practitioner, a facility, or other

entity (other than a provider of services) that furnishes items or services under Medicare.

Vacate means to set aside a previous action.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009; 80 FR 10617, Feb. 27, 2015]

§ 405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) *General overview*—(1) *Entitlement appeals.* The SSA makes an initial determination on an application for Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an Administrative Law Judge (ALJ) under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, he or she may request the Medicare Appeals Council (MAC) to review the case. Following the action of the MAC, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request, and the ALJ will conduct a hearing if the amount remaining in controversy and other requirements for an ALJ hearing are met. If the beneficiary is dissatisfied with the decision of the ALJ, he or she may request the MAC to review the case. If the MAC reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

(b) *Non-beneficiary appellants.* In general, the procedures described in paragraph (a) of this section are also available to parties other than beneficiaries either directly or through a representative acting on a party's behalf, consistent with the requirements of this subpart I. A provider generally has the right to judicial review only as provided under section 1879(d) of the Act; that is, when a determination involves a finding that services are not covered because—

(1) They were custodial care (see § 411.15(g) of this chapter); they were not reasonable and necessary (see § 411.15(k) of this chapter); they did not qualify as covered home health services because the beneficiary was not confined to the home or did not need skilled nursing care on an intermittent basis (see § 409.42(a) and (c)(1) of this chapter); or they were hospice services provided to a non-terminally ill individual (see § 418.22 of this chapter); and

(2) Either the provider or the beneficiary, or both, knew or could reasonably be expected to know that those services were not covered under Medicare.

§ 405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews.

(a) *Parties to the initial determination.* The parties to the initial determination are the following individuals and entities:

(1) A beneficiary who files a claim for payment under Medicare Part A or Part B or has had a claim for payment filed on his or her behalf, or in the case of a deceased beneficiary, when there is no estate, any person obligated to make or entitled to receive payment in accordance with part 424, subpart E of this chapter. Payment by a third party payer does not entitle that entity to party status.

(2) A supplier who has accepted assignment for items or services furnished to a beneficiary that are at issue in the claim.

(3) A provider of services who files a claim for items or services furnished to a beneficiary.

(4) An applicable plan for an initial determination under § 405.924(b)(16) where Medicare is pursuing recovery directly from the applicable plan. The applicable plan is the sole party to an initial determination under § 405.924(b)(16) (that is, where Medicare is pursuing recovery directly from the applicable plan).

(b) *Parties to the redetermination, reconsideration, hearing and MAC.* The parties to the redetermination, reconsideration, hearing, and MAC review are—

(1) The parties to the initial determination in accordance with paragraph (a) of this section, except under paragraph (a)(1) of this section where a beneficiary has assigned appeal rights under § 405.912;

(2) A State agency in accordance with § 405.908;

(3) A provider or supplier that has accepted an assignment of appeal rights from the beneficiary according to § 405.912;

(4) A non-participating physician not billing on an assigned basis who, in accordance with section 1842(l) of the Act, may be liable to refund monies collected for services furnished to the beneficiary because those services were denied on the basis of section 1862(a)(1) of the Act; and

(5) A non-participating supplier not billing on an assigned basis who, in accordance with sections 1834(a)(18) and 1834(j)(4) of the Act, may be liable to refund monies collected for items furnished to the beneficiary.

(c) *Appeals by providers and suppliers when there is no other party available.* If a provider or supplier is not already a party to the proceeding in accordance with paragraphs (a) and (b) of this section, a provider of services or supplier may appeal an initial determination relating to services it rendered to a beneficiary who subsequently dies if there is no other party available to appeal the determination. This paragraph (c) does not apply to an initial determination with respect to an applicable plan under § 405.924(b)(16).

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015]

§ 405.908 Medicaid State agencies.

When a beneficiary is enrolled to receive benefits under both Medicare and Medicaid, the Medicaid State agency may file a request for an appeal with respect to a claim for items or services furnished to a dually eligible beneficiary only for services for which the Medicaid State agency has made payment, or for which it may be liable. A Medicaid State agency is considered a party only when it files a timely redetermination request with respect to a claim for items or services furnished to a beneficiary in accordance with 42 CFR parts 940 through 958. If a State agency files a request for redetermination, it may retain party status at the QIC, ALJ, MAC, and judicial review levels.

§ 405.910 Appointed representatives.

(a) *Scope of representation.* An appointed representative may act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. Appointed representatives do not have party status and may take action only on behalf of the individual or entity that they represent.

(b) *Persons not qualified.* A party may not name as an appointed representative, an individual who is disqualified, suspended, or otherwise prohibited by law from acting as a representative in any proceedings before DHHS, or in entitlement appeals, before SSA.

(c) *Completing a valid appointment.* For purposes of this subpart, an appointment of representation must:

(1) Be in writing and signed and dated by both the party and individual agreeing to be the representative;

(2) Provide a statement appointing the representative to act on behalf of the party, and in the case of a beneficiary, authorizing the adjudicator to release identifiable health information to the appointed representative.

(3) Include a written explanation of the purpose and scope of the representation;

(4) Contain both the party's and appointed representative's name, phone number, and address;

(5) Identify the beneficiary's Medicare health insurance claim number

when the beneficiary is the party appointing a representative;

(6) Include the appointed representative's professional status or relationship to the party;

(7) Be filed with the entity processing the party's initial determination or appeal.

(d) *Curing a defective appointment of representative.* (1) If any one of the seven elements named in paragraph (c) of this section is missing from the appointment, the adjudicator should contact the party and provide a description of the missing documentation or information.

(2) Unless the defect is cured, the prospective appointed representative lacks the authority to act on behalf of the party, and is not entitled to obtain or receive any information related to the appeal, including the appeal decision.

(e) *Duration of appointment.* (1) Unless revoked, an appointment is considered valid for 1 year from the date that the Appointment of Representative (AOR) form or other conforming written instrument contains the signatures of both the party and the appointed representative.

(2) To initiate an appeal within the 1-year time frame, the representative must file a copy of the AOR form, or other conforming written instrument, with the appeal request. Unless revoked, the representation is valid for the duration of an individual's appeal of an initial determination.

(3) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed in connection with the party's efforts to make a claim for third party payment is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

(4) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed by an applicable plan which has party status in accordance with § 405.906(a)(1)(iv) is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

(f) *Appointed representative fees*—(1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the ALJ level are not considered proceedings before the Secretary.

(2) *No fees or costs against trust funds.* No award of attorney or any other representative's fees or any costs in connection with an appeal may be made against the Medicare trust funds.

(3) *Special rules for providers and suppliers.* A provider or supplier that furnished the items or services to a beneficiary that are the subject of the appeal may represent that beneficiary in an appeal under this subpart, but the provider or supplier may not charge the beneficiary any fee associated with the representation. If a provider or supplier furnishes services or items to a beneficiary, the provider or supplier may not represent the beneficiary on the issues described in section 1879(a)(2) of the Act, unless the provider or supplier waives the right to payment from the beneficiary for the services or items involved in the appeal.

(4) *Special rules for purposes of third party payment.* The Secretary does not review fee arrangements made by a beneficiary for purposes of making a claim for third party payment (as defined in 42 CFR 411.21) even though the representation may ultimately include representation for a Medicare Secondary Payer recovery claim.

(5) *Reasonableness of representative fees.* In determining the reasonableness of a representative's fee, the Secretary will not apply the test specified in sections 206(a)(2) and (a)(3) of the Act.

(g) *Responsibilities of an appointed representative.* (1) An appointed representative has an affirmative duty to—

(i) Inform the party of the scope and responsibilities of the representation;

(ii) Inform the party of the status of the appeal and the results of actions taken on behalf of the party, including, but not limited to, notification of appeal determinations, decisions, and further appeal rights;

(iii) Disclose to a beneficiary any financial risk and liability of a non-assigned claim that the beneficiary may have;

(iv) Not act contrary to the interest of the party; and

(v) Comply with all laws and CMS regulations, CMS Rulings, and instructions.

(2) An appeal request filed by a provider or supplier described in paragraph (f)(3) of this section must also include a statement signed by the provider or supplier stating that no financial liability is imposed on the beneficiary in connection with that representation. If applicable, the appeal request must also include a signed statement that the provider or supplier waives the right to payment from the beneficiary for services or items regarding issues described in section 1879(a)(2) of the Act.

(h) *Authority of an appointed representative.* An appointed representative may, on behalf of the party—

(1) Obtain appeals information about the claim to the same extent as the party;

(2) Submit evidence;

(3) Make statements about facts and law; and

(4) Make any request, or give, or receive, any notice about the appeal proceedings.

(i) *Notice or request to an appointed representative*—(1) *Initial determinations.* When a contractor takes an action or issues an initial determination, it sends the action or notice to the party.

(2) *Appeals.* When a contractor, QIC, ALJ, or the MAC takes an action or issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or MAC sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

(4) For initial determinations and appeals involving Medicare Secondary Payer recovery claims where the beneficiary is a party, the adjudicator sends notices and requests to both the beneficiary and the beneficiary's representative, if the beneficiary has a representative.

(j) *Effect of notice or request to an appointed representative.* A notice or request sent to the appointed representative has the same force and effect as if was sent to the party.

(k) *Information available to the appointed representative.* An appointed representative may obtain any and all appeals information applicable to the claim at issue that is available to the party.

(l) *Delegation of appointment by appointed representative.* An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(1) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual. The notice must include:

(i) The name of the designee; and

(ii) The designee's acceptance to be obligated and comply with the requirements of representation under this subpart.

(2) The party accepts the designation as evidenced by a written statement signed by the party. This signed statement is not required when the appointed representative and designee are attorneys in the same law firm or organization.

(m) *Revoking the appointment of representative.* (1) A party may revoke an appointment of representative without cause at any time.

(2) *Revocation.* Revocation is not effective until the adjudicator receives a signed, written statement from the party.

(3) *Death of the party.* (i) The death of a party terminates the authority of the appointed representative, except as specified in paragraph (m)(3)(ii) of this section.

(ii) A party's death does not terminate an appeal that is in progress if another individual or entity may be entitled to receive or obligated to make payment for the items or services that are the subject of the appeal. The appointment of representative remains in effect for the duration of the appeal except for MSP recovery claims.

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015]

§ 405.912 Assignment of appeal rights.

(a) *Who may be an assignee.* Only a provider, or supplier that—

(1) Is not a party to the initial determination as defined in § 405.906; and

(2) Furnished an item or service to the beneficiary may seek assignment of appeal rights from the beneficiary for that item or service.

(b) *Who may not be an assignee.* An individual or entity who is not a provider or supplier may not be an assignee. A provider or supplier that furnishes an item or service to a beneficiary may not seek assignment for that item or service when considered a party to the initial determination as defined in § 405.906.

(c) *Requirements for a valid assignment of appeal right.* The assignment of appeal rights must—

(1) Be executed using a CMS standard form;

(2) Be in writing and signed by both the beneficiary assigning his or her appeal rights and by the assignee;

(3) Indicate the item or service for which the assignment of appeal rights is authorized;

(4) Contain a waiver of the assignee's right to collect payment from the assignor for the specific item or service that are the subject of the appeal except as set forth in paragraph (d)(2) of this section; and

(5) Be submitted at the same time the request for redetermination or other appeal is filed.

(d) *Waiver of right to collect payment.* (1) Except as specified in paragraph (d)(2) of this section, the assignee must waive the right to collect payment for the item or service for which the assignment of appeal rights is made. If the assignment is revoked under paragraph (g)(2) or (g)(3) of this section, the waiver of the right to collect payment nevertheless remains valid. A waiver of the right to collect payment remains in effect regardless of the outcome of the appeal decision.

(2) The assignee is not prohibited from recovering payment associated with coinsurance or deductibles or when an advance beneficiary notice is properly executed.

(e) *Duration of a valid assignment of appeal rights.* Unless revoked, the assignment of appeal rights is valid for all administrative and judicial review associated with the item or service as indicated on the standard CMS form, even in the event of the death of the assignor.

(f) *Rights of the assignee.* When a valid assignment of appeal rights is executed, the assignor transfers all appeal rights involving the particular item or service to the assignee. These include, but are not limited to—

(1) Obtaining information about the claim to the same extent as the assignor;

(2) Submitting evidence;

(3) Making statements about facts or law; and

(4) Making any request, or giving, or receiving any notice about appeal proceedings.

(g) *Revocation of assignment.* When an assignment of appeal rights is revoked, the rights to appeal revert to the assignor. An assignment of appeal rights may be revoked in any of the following ways:

(1) *In writing by the assignor.* The revocation of assignment must be delivered to the adjudicator and the assignee, and is effective on the date of receipt by the adjudicator.

(2) By abandonment if the assignee does not file an appeal of an unfavorable decision.

(3) By act or omission by the assignee that is determined by an adjudicator to be contrary to the financial interests of the assignor.

(h) *Responsibilities of the assignee.* Once the assignee files an appeal, the assignee becomes a party to the appeal. The assignee must meet all requirements for appeals that apply to any other party.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

INITIAL DETERMINATIONS

§ 405.920 Initial determinations.

After a claim is filed with the appropriate contractor in the manner and form described in subpart C of part 424 of this chapter, the contractor must—

(a) Determine if the items and services furnished are covered or otherwise reimbursable under title XVIII of the Act;

(b) Determine any amounts payable and make payment accordingly; and

(c) Notify the parties to the initial determination of the determination in accordance with § 405.921.

§ 405.921 Notice of initial determination.

(a) *Notice of initial determination sent to the beneficiary.* (1) The notice must be written in a manner calculated to be understood by the beneficiary, and sent to the last known address of the beneficiary.

(2) *Content of the notice.* The notice of initial determination must contain all of the following:

(i) The reasons for the determination, including whether a local medical review policy, a local coverage determination, or national coverage determination was applied.

(ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination.

(iii) Information on the right to a redetermination if the beneficiary is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination.

(iv) Any other requirements specified by CMS.

(b) *Notice of initial determination sent to providers and suppliers.* (1) An electronic or paper remittance advice (RA) notice is the notice of initial determination sent to providers and suppliers that accept assignment.

(i) The electronic RA must comply with the format and content requirements of the standard adopted for national use by covered entities under the Health Insurance Portability and Accountability Act (HIPAA) and related CMS manual instructions.

(ii) When a paper RA is mailed, it must comply with CMS manual instructions that parallel the HIPAA data content and coding requirements.

(2) The notice of initial determination must contain all of the following:

(i) The basis for any full or partial denial determination of services or items on the claim.

(ii) Information on the right to a redetermination if the provider or supplier is dissatisfied with the outcome of the initial determination.

(iii) All applicable claim adjustment reason and remark codes to explain the determination.

(iv) The source of the RA and who may be contacted if the provider or supplier requires further information.

(v) All content requirements of the standard adopted for national use by covered entities under HIPAA.

(vi) Any other requirements specified by CMS.

(c) *Notice of initial determination sent to an applicable plan*—(1) *Content of the notice.* The notice of initial determination under § 405.924(b)(16) must contain all of the following:

(i) The reasons for the determination.

(ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination.

(iii) Information on the right to a redetermination if the liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination.

(iv) Any other requirements specified by CMS.

(2) [Reserved]

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015]

§ 405.922 Time frame for processing initial determinations.

The contractor issues initial determinations on clean claims within 30 calendar days of receipt if they are submitted by or on behalf of the beneficiary who received the items and/or services; otherwise, interest must be paid at the rate specified at 31 U.S.C. 3902(a) for the period beginning on the day after the required payment date and ending on the date payment is made.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009]

§ 405.924 Actions that are initial determinations.

(a) *Applications and entitlement of individuals.* SSA makes initial determinations and processes reconsiderations with respect to an individual on the following:

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance under Medicare.

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence requested by SSA to support the application. (SSA specifies in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence).

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance, or a denial of a request for cancellation of a request for withdrawal.

(4) A determination as to whether an individual, previously determined as entitled to hospital or supplementary medical insurance, is no longer entitled to those benefits, including a determination based on nonpayment of premiums.

(b) *Claims made by or on behalf of beneficiaries.* The Medicare contractor makes initial determinations regarding claims for benefits under Medicare Part A and Part B. A finding that a request for payment or other submission does not meet the requirements for a Medicare claim as defined in § 424.32 of this chapter, is not considered an initial determination. An initial determination for purposes of this subpart includes, but is not limited to, determinations with respect to any of the following:

(1) If the items and/or services furnished are covered under title XVIII.

(2) In the case of determinations on the basis of section 1879(b) or (c) of the Act, if the beneficiary, or supplier who accepts assignment under § 424.55 of this chapter knew, or could reasonably have expected to know at the time the items or services were furnished, that the items or services were not covered.

(3) In the case of determinations on the basis of section 1842(l)(1) of the Act, if the beneficiary or physician knew, or could reasonably have expected to know at the time the services were furnished, that the services were not covered.

(4) Whether the deductible is met.

(5) The computation of the coinsurance amount.

(6) The number of days used for inpatient hospital, psychiatric hospital, or post-hospital extended care.

(7) Periods of hospice care used.

(8) Requirements for certification and plan of treatment for physician services, durable medical equipment, therapies, inpatient hospitalization, skilled nursing care, home health, hospice, and partial hospitalization services.

(9) The beginning and ending of a spell of illness, including a determination made under the presumptions established under § 409.60(c)(2) of this chapter, and as specified in § 409.60(c)(4) of this chapter.

(10) The medical necessity of services, or the reasonableness or appropriateness of placement of an individual at an acute level of patient care made by the Quality Improvement Organization (QIO) on behalf of the contractor in accordance with § 476.86(c)(1) of this chapter.

(11) Any other issues having a present or potential effect on the amount of benefits to be paid under Part A or Part B of Medicare, including a determination as to whether there was an underpayment of benefits paid under Part A or Part B, and if so, the amount thereof.

(12) If a waiver of adjustment or recovery under sections 1870(b) and (c) of the Act is appropriate—

(i) When an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) was made for an individual; or

(ii) For a Medicare Secondary Payer recovery claim against a beneficiary or against a provider or supplier.

(13) If a particular claim is not payable by Medicare based upon the application of the Medicare Secondary Payer provisions of section 1862(b) of the Act.

(14) Under the Medicare Secondary Payer provisions of sections 1862(b) of

the Act that Medicare has a recovery claim against a provider, supplier, or beneficiary for services or items that were already paid by the Medicare program, except when the Medicare Secondary Payer recovery claim against the provider or supplier is based upon failure to file a proper claim as defined in part 411 of this chapter because this action is a reopening.

(15) A claim not payable to a beneficiary for the services of a physician who has opted-out.

(16) Under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery claim if Medicare is pursuing recovery directly from an applicable plan. That is, there is an initial determination with respect to the amount and existence of the recovery claim.

(c) *Determinations by QIOs.* An initial determination for purposes of this subpart also includes a determination made by a QIO that:

(1) A provider can terminate services provided to an individual when a physician certified that failure to continue the provision of those services is likely to place the individual's health at significant risk; or

(2) A provider can discharge an individual from the provider of services.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009; 79 FR 68001, Nov. 13, 2014; 80 FR 10618, Feb. 27, 2015]

§ 405.925 Decisions of utilization review committees.

(a) *General rule.* A decision of a utilization review committee is a medical determination by a staff committee of the provider or a group similarly composed and does not constitute a determination by the Secretary within the meaning of section 1869 of the Act. The decision of a utilization review committee may be considered by CMS along with other pertinent medical evidence in determining whether or not an individual has the right to have payment made under Part A of title XVIII.

(b) *Applicability under the prospective payment system.* CMS may consider utilization review committee decisions related to inpatient hospital services paid for under the prospective payment system (see part 412 of this chapter) only as those decisions concern:

(1) The appropriateness of admissions resulting in payments under subparts D, E and G of part 412 of this chapter.

(2) The covered days of care involved in determinations of outlier payments under § 412.80(a)(1)(i) of this chapter; and

(3) The necessity of professional services furnished in high cost outliers under § 412.80(a)(1)(ii) of this chapter.

[48 FR 39831, Sept. 1, 1983. Redesignated at 77 FR 29028, May 16, 2012]

§ 405.926 Actions that are not initial determinations.

Actions that are not initial determinations and are not appealable under this subpart include, but are not limited to the following:

(a) Any determination for which CMS has sole responsibility, for example one of the following:

(1) If an entity meets the conditions for participation in the program.

(2) If an independent laboratory meets the conditions for coverage of services.

(3) Determination under the Medicare Secondary Payer provisions of section 1862(b) of the Act of the debtor for a particular recovery claim.

(b) The coinsurance amounts prescribed by regulation for outpatient services under the prospective payment system.

(c) Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A.

(d) Whether an individual's appeal meets the qualifications for expedited access to judicial review provided in § 405.990.

(e) Any determination regarding whether a Medicare overpayment claim must be compromised, or collection action terminated or suspended under the Federal Claims Collection Act of 1966, as amended.

(f) Determinations regarding the transfer or discharge of residents of

skilled nursing facilities in accordance with § 483.12 of this chapter.

(g) Determinations regarding the readmission screening and annual resident review processes required by subparts C and E of part 483 of this chapter.

(h) Determinations for a waiver of Medicare Secondary Payer recovery under section 1862(b) of the Act.

(i) Determinations for a waiver of interest.

(j) Determinations for a finding regarding the general applicability of the Medicare Secondary Payer provisions (as opposed to the application of these provisions to a particular claim or claims for Medicare payment for benefits).

(k) Except as specified in § 405.924(b)(16), determinations under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery against an entity that was or is required or responsible (directly, as an insurer or self-insurer; as a third party administrator; as an employer that sponsors, contributes to or facilitates a group health plan or a large group health plan; or otherwise) to make payment for services or items that were already reimbursed by the Medicare program.

(l) A contractor's, QIC's, ALJ's, or MAC's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, hearing decision, or review decision.

(m) Determinations that CMS or its contractors may participate in or act as parties in an ALJ hearing or MAC review.

(n) Determinations that a provider or supplier failed to submit a claim timely or failed to submit a timely claim despite being requested to do so by the beneficiary or the beneficiary's subrogee.

(o) Determinations with respect to whether an entity qualifies for an exception to the electronic claims submission requirement under part 424 of this chapter.

(p) Determinations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act.

(q) A contractor's prior determination related to coverage of physicians' services.

(r) Requests for anticipated payment under the home health prospective payment system under § 409.43(c)(ii)(2) of this chapter.

(s) Claim submissions on forms or formats that are incomplete, invalid, or do not meet the requirements for a Medicare claim and returned or rejected to the provider or supplier.

(t) A contractor's prior authorization determination related to coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

(u) Issuance of notice to an individual entitled to Medicare benefits under Title XVIII of the Act when such individual received observation services as an outpatient for more than 24 hours, as specified under § 489.20(y) of this chapter.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 80 FR 10618, Feb. 27, 2015; 80 FR 81706, Dec. 30, 2015; 81 FR 57267, Aug. 22, 2016]

§ 405.927 Initial determinations subject to the reopenings process.

Minor errors or omissions in an initial determination must be corrected only through the contractor's reopenings process under § 405.980(a)(3).

§ 405.928 Effect of the initial determination.

(a) An initial determination described in § 405.924(a) is binding unless it is revised or reconsidered in accordance with 20 CFR 404.907, or revised as a result of a reopening in accordance with 20 CFR 404.988.

(b) An initial determination described in § 405.924(b) is binding upon all parties to the initial determination unless—

(1) A redetermination is completed in accordance with § 405.940 through § 405.958; or

(2) The initial determination is revised as a result of a reopening in accordance with § 405.980.

(c) An initial determination listed in § 405.924(b) where a party submits a timely, valid request for redetermination under § 405.942 through § 405.944 must be processed as a redetermination

under § 405.948 through § 405.958 unless the initial determination involves a clerical error or other minor error or omission.

REDETERMINATIONS

§ 405.940 Right to a redetermination.

A person or entity that may be a party to a redetermination in accordance with § 405.906(b) and that is dissatisfied with an initial determination may request a redetermination by a contractor in accordance with § 405.940 through § 405.958, regardless of the amount in controversy.

§ 405.942 Time frame for filing a request for a redetermination.

(a) *Time frame for filing a request.* Except as provided in paragraph (b) of this section, any request for redetermination must be filed within 120 calendar days from the date a party receives the notice of the initial determination.

(1) For purposes of this section, the date of receipt of the initial determination will be presumed to be 5 calendar days after the date of the notice of initial determination, unless there is evidence to the contrary.

(2) The request is considered as filed on the date it is received by the contractor.

(b) *Extending the time frame for filing a request. General rule.* If the 120 calendar day period in which to file a request for a redetermination has expired and a party shows good cause, the contractor may extend the time frame for filing a request for redetermination.

(1) *How to request an extension.* A party may file a request for an extension of time for filing a request for a redetermination with the contractor. The party should include any evidence supporting the request for extension. The request for redetermination extension must—

(i) Be in writing;

(ii) State why the request for redetermination was not filed within the required time frame; and

(iii) Meet the requirements of § 405.944.

(2) *How the contractor determines if good cause exists.* In determining if a party has good cause for missing a deadline to request a redetermination, the contractor considers—

(i) The circumstances that kept the party from making the request on time;

(ii) If the contractor's action(s) misled the party; and

(iii) If the party had or has any physical, mental, educational, or linguistic limitations, including any lack of facility with the English language, that prevented the party from filing a timely request or from understanding or knowing about the need to file a timely request.

(3) *Examples of good cause.* Examples of circumstances when good cause may be found to exist include, but are not limited to, the following situations:

(i) The party was prevented by serious illness from contacting the contractor in person, in writing, or through a friend, relative, or other person; or

(ii) The party had a death or serious illness in his or her immediate family; or

(iii) Important records of the party were destroyed or damaged by fire or other accidental cause; or

(iv) The contractor gave the party incorrect or incomplete information about when and how to request a redetermination; or

(v) The party did not receive notice of the determination or decision; or

(vi) The party sent the request to a Government agency in good faith within the time limit, and the request did not reach the appropriate contractor until after the time period to file a request expired.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009]

§ 405.944 Place and method of filing a request for a redetermination.

(a) *Filing location.* The request for redetermination must be filed with the contractor indicated on the notice of initial determination.

(b) *Content of redetermination request.* The request for redetermination must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements as follows:

(1) The beneficiary's name;

(2) The Medicare health insurance claim number;

(3) Specific service(s) and/or item(s) for which the redetermination is being requested and the specific date(s) of the service;

(4) The name and signature of the party or the representative of the party.

(c) *Requests for redetermination by more than one party*. If more than one party timely files a request for redetermination on the same claim before a redetermination is made on the first timely filed request, the contractor must consolidate the separate requests into one proceeding and issue one redetermination.

§405.946 Evidence to be submitted with the redetermination request.

(a) *Evidence submitted with the request*. When filing the request for redetermination, a party must explain why it disagrees with the contractor's determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination.

(b) *Evidence submitted after the request*. When a party submits additional evidence after filing the request for redetermination, the contractor's 60 calendar day decision-making time frame is automatically extended for up to 14 calendar days for each submission.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65333, Dec. 9, 2009]

§405.947 Notice to the beneficiary of applicable plan's request for a redetermination.

(a) A CMS contractor must send notice of the applicable plan's appeal to the beneficiary.

(b) Issuance and content of the notice must comply with CMS instructions.

[80 FR 10618, Feb. 27, 2015]

§405.948 Conduct of a redetermination.

A redetermination consists of an independent review of an initial determination. In conducting a redetermination, the contractor reviews the evidence and findings upon which the initial determination was based, and any additional evidence the parties submit or the contractor obtains on its own. An individual who was not involved in making the initial determination must make a redetermination. The contractor may raise and develop new issues that are relevant to the claims in the particular case.

§405.950 Time frame for making a redetermination.

(a) *General rule*. The contractor mails, or otherwise transmits, written notice of the redetermination or dismissal to the parties to the redetermination at their last known addresses within 60 calendar days of the date the contractor receives a timely filed request for redetermination.

(b) *Exceptions*. (1) If a contractor grants an appellant's request for an extension of the 120 calendar day filing deadline made in accordance with §405.942(b), the 60 calendar day decision-making time frame begins on the date the contractor receives the late-filed request for redetermination, or when the request for an extension is granted, whichever is later.

(2) If a contractor receives from multiple parties timely requests for redetermination of a claim determination, consistent with §405.944(c), the contractor must issue a redetermination or dismissal within 60 calendar days of the latest filed request.

(3) If a party submits additional evidence after the request for redetermination is filed, the contractor's 60 calendar day decision-making time frame is extended for up to 14 calendar days for each submission, consistent with §405.946(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65333, Dec. 9, 2009]

§405.952 Withdrawal or dismissal of a request for a redetermination.

(a) *Withdrawing a request*. A party that files a request for redetermination may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must contain a clear statement that the appellant is withdrawing the request for a redetermination and does not intend to proceed further with the appeal. The request must be received in

the contractor's mailroom before a redetermination is issued. The appeal will proceed with respect to any other parties that have filed a timely request for redetermination.

(b) *Dismissing a request.* A contractor dismisses a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 405.906(b) or does not otherwise have a right to a redetermination under section 1869(a) of the Act;

(2) When the contractor determines the party failed to make out a valid request for redetermination that substantially complies with § 405.944;

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with § 405.942;

(4) When a beneficiary or the beneficiary's representative files a request for redetermination, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the contractor considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party filed a valid and timely redetermination request under §§ 405.942 and 405.944;

(5) When a party filing the redetermination request submits a timely written request for withdrawal with the contractor; or

(6) When the contractor has not issued an initial determination on the claim or the matter for which a redetermination is sought.

(c) *Notice of dismissal.* A contractor mails or otherwise transmits a written notice of the dismissal of the redetermination request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a contractor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for redetermination is binding unless it is modified or reversed by a QIC under § 405.974(b) or vacated under paragraph (d) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009]

§ 405.954 Redetermination.

Upon the basis of the evidence of record, the contractor adjudicates the claim(s), and renders a redetermination affirming or reversing, in whole or in part, the initial determination in question.

§ 405.956 Notice of a redetermination.

(a) *Notification to parties*—(1) *General rule.* Written notice of a redetermination affirming, in whole or in part, the initial determination must be mailed or otherwise transmitted to all parties at their last known addresses in accordance with the time frames established in § 405.950. Written notice of a redetermination fully reversing the initial determination must be mailed or otherwise transmitted to the appellant in accordance with the time frames established in § 405.950. If the redetermination results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.* In an overpayment case involving multiple beneficiaries who have no liability, the contractor may issue a written notice only to the appellant.

(b) *Content of the notice for affirmations, in whole or in part.* For decisions that are affirmations, in whole or in part, of the initial determination, the redetermination must be written in a manner calculated to be understood by a beneficiary, and contain—

(1) A clear statement indicating the extent to which the redetermination is favorable or unfavorable;

(2) A summary of the facts, including, as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case;

(4) A summary of the rationale for the redetermination in clear, understandable language;

(5) Notification to the parties of their right to a reconsideration and a description of the procedures that a party must follow in order to request a reconsideration, including the time frame within which a reconsideration must be requested;

(6) A statement of any specific missing documentation that must be submitted with a request for a reconsideration, if applicable;

(7) A statement that all evidence the appellant wishes to introduce during the claim appeals process should be submitted with the request for a reconsideration;

(8) Notification that evidence not submitted to the QIC as indicated in paragraph (b)(6) of this section, is not considered at an ALJ hearing or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously; and

(9) The procedures for obtaining additional information concerning the redetermination, such as specific provisions of the policy, manual, or regulation used in making the redetermination.

(10) Any other requirements specified by CMS.

(c) *Content of the notice for a full reversal.* For decisions that are full reversals of the initial determination, the redetermination must be in writing and contain—

(1) A clear statement indicating that the redetermination is wholly favorable;

(2) Any other requirements specified by CMS.

(d) *Exception for beneficiary appeal requests.* (1) The notice must inform beneficiary appellants that the requirements of paragraph (b)(8) of this section are not applicable for purposes of beneficiary appeals.

(2) This exception does not apply for appeal requests from beneficiaries who are represented by providers or suppliers.

§ 405.958 Effect of a redetermination.

In accordance with section 1869(a)(3)(D) of the Act, once a redetermination is issued, it becomes part of the initial determination. The redetermination is binding upon all parties unless—

(a) A reconsideration is completed in accordance with § 405.960 through § 405.978; or

(b) The redetermination is revised as a result of a reopening in accordance with § 405.980.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009]

RECONSIDERATION

§ 405.960 Right to a reconsideration.

A person or entity that is a party to a redetermination made by a contractor as described under § 405.940 through § 405.958, and is dissatisfied with that determination, may request a reconsideration by a QIC in accordance with § 405.962 through § 405.966, regardless of the amount in controversy.

§ 405.962 Timeframe for filing a request for a reconsideration.

(a) *Timeframe for filing a request.* Except as provided in paragraph (b) of this section and in § 405.974(b)(1), regarding a request for QIC reconsideration of a contractor's dismissal of a redetermination request, any request for a reconsideration must be filed within 180 calendar days from the date the party receives the notice of the redetermination.

(1) For purposes of this section, the date of receipt of the redetermination will be presumed to be 5 calendar days after the date of the notice of redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 180 calendar day filing deadline, the request is considered as filed on the date it is received by the QIC.

(b) *Extending the time for filing a request*—(1) *General rule.* A QIC may extend the 180 calendar day timeframe for filing a request for reconsideration for good cause.

(2) *How to request an extension.* A party to the redetermination must file its request for an extension of the time for filing the reconsideration request with its request for reconsideration. A party should include evidence to support the request for extension. The request for reconsideration and request for extension must—

(i) Be in writing;

(ii) State why the request for reconsideration was not filed within the required timeframe; and

(iii) Meet the requirements of § 405.964.

(3) *How the QIC determines whether good cause exists.* In determining whether a party has good cause for missing a deadline to request reconsideration, the QIC applies the good cause provisions contained in § 405.942(b)(2) and (b)(3).

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

§ 405.964 Place and method of filing a request for a reconsideration.

(a) *Filing location.* The request for reconsideration must be filed with the QIC indicated on the notice of redetermination.

(b) *Content of reconsideration request.* The request for reconsideration must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements, as follows:

(1) The beneficiary's name;

(2) Medicare health insurance claim number;

(3) Specific service(s) and item(s) for which the reconsideration is requested and the specific date(s) of service;

(4) The name and signature of the party or the representative of the party; and

(5) The name of the contractor that made the redetermination.

(c) *Requests for reconsideration by more than one party.* If more than one party timely files a request for reconsideration on the same claim before a reconsideration is made on the first timely filed request, the QIC must consolidate the separate requests into one proceeding and issue one reconsideration.

§ 405.966 Evidence to be submitted with the reconsideration request.

(a) *Evidence submitted with the request.* When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination.

(1) This evidence must include any missing documentation identified in the notice of redetermination, consistent with § 405.956(b)(6).

(2) Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence.

(b) *Evidence submitted after the request.* Each time a party submits additional evidence after filing the request for reconsideration, the QIC's 60 calendar day decisionmaking timeframe is automatically extended by up to 14 calendar days for each submission. This extension does not apply to timely submissions of documentation specifically requested by a QIC, unless the documentation was originally requested in the notice of redetermination.

(c) *Exception for beneficiaries and State Medicaid Agencies that file reconsideration requests.* (1) Beneficiaries and State Medicaid Agencies that file requests for reconsideration are not required to comply with the requirements of paragraph (a) of this section. However, the automatic 14 calendar day extension described in paragraph (b) of this section applies to each evidence submission made after the request for reconsideration is filed.

(2) Beneficiaries who are represented by providers or suppliers must comply with the requirements of paragraph (a) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

§ 405.968 Conduct of a reconsideration.

(a) *General rules.* (1) A reconsideration consists of an independent, on-

the-record review of an initial determination, including the redetermination and all issues related to payment of the claim. In conducting a reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own. If the initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), a QIC's reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable.

(b) *Authority of the QIC.* (1) National coverage determinations (NCDs), CMS Rulings, and applicable laws and regulations are binding on the QIC.

(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.

(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.

(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.

(5) A QIC may raise and develop new issues that are relevant to the claims in a particular case provided that the contractor rendered a redetermination with respect to the claims.

(c) *Qualifications of the QIC's panel members.* (1) Members of a QIC's panel who conduct reconsiderations must have sufficient medical, legal, and other expertise, including knowledge of the Medicare program.

(2) When a redetermination is made with respect to whether an item or service is reasonable and necessary (section 1862(a)(1)(A) of the Act), the QIC designates a panel of physicians or other appropriate health care professionals to consider the facts and circumstances of the redetermination.

(3) Where a claim pertains to the furnishing of treatment by a physician, or the provision of items or services by a physician, a reviewing professional must be a physician.

(d) *Disqualification of a QIC panel member.* No physician or health care professional employed by or otherwise working for a QIC may review determinations regarding—

(1) Health care services furnished to a patient if that physician or health care professional was directly responsible for furnishing those services; or

(2) Health care services provided in or by an institution, organization, or agency, if that physician or health care professional or any member of the physician's family or health care professional's family has, directly or indirectly, a significant financial interest in that institution, organization, or agency (see the term family member as defined in § 405.902).

§ 405.970 Timeframe for making a reconsideration.

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration or any additional time provided by paragraph (b) of this section, the QIC mails, or otherwise transmits to the parties at their last known addresses, written notice of—

(1) The reconsideration;

(2) Its inability to complete its review within 60 calendar days in accordance with paragraphs (c) through (e) of this section; or

(3) Dismissal.

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180 calendar day filing deadline made in accordance with § 405.962(b), the QIC's 60 calendar day decision-making timeframe begins on the date the QIC receives the late filed request for reconsideration, or when the request for an extension that meets the

requirements of § 405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration from multiple parties, consistent with § 405.964(c), the QIC must issue a reconsideration, notice that it cannot complete its review, or dismissal within 60 calendar days for each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration is filed, the QIC's 60 calendar day decisionmaking timeframe is extended by up to 14 calendar days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 calendar days of receiving a request for a reconsideration, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

(1) Notify all parties of its reconsideration, consistent with § 405.976.

(2) Notify the parties that it cannot complete the reconsideration by the deadline specified in paragraph (b) of this section and offer the appellant the opportunity to escalate the appeal to an ALJ. The QIC continues to process the reconsideration unless it receives a written request from the appellant to escalate the case to an ALJ after the adjudication period has expired.

(d) *Responsibilities of the appellant.* If an appellant wishes to exercise the option of escalating the case to an ALJ, the appellant must notify the QIC in writing.

(e) *Actions following appellant's notice.* (1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration and notifies the appellant of its action consistent with § 405.972 or § 405.976.

(2) If the appellant notifies the QIC that the appellant wishes to escalate the case, the QIC must take one of the following actions within 5 calendar days of receipt of the notice or 5 calendar days from the end of the applicable adjudication period under paragraph (a) or (b) of this section:

(i) Complete its reconsideration and notify all parties of its decision consistent with § 405.972 or § 405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to the ALJ hearing office.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65334, Dec. 9, 2009]

§ 405.972 Withdrawal or dismissal of a request for a reconsideration.

(a) *Withdrawing a request.* An appellant that files a request for reconsideration may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must—

(1) Contain a clear statement that the appellant is withdrawing the request for reconsideration and does not intend to proceed further with the appeal.

(2) Be received in the QIC's mailroom before the reconsideration is issued.

(b) *Dismissing a request.* A QIC dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting reconsideration is not a proper party under § 405.906(b) or does not otherwise have a right to a reconsideration under section 1869(b) of the Act;

(2) When the QIC determines that the party failed to make out a valid request for reconsideration that substantially complies with § 405.964(a) and (b);

(3) When the party fails to file the reconsideration request in accordance with the timeframes established in § 405.962, or fails to file the request for reconsideration of a contractor's dismissal of a redetermination request in accordance with the timeframes established in § 405.974(b)(1);

(4) When a beneficiary or the beneficiary's representative files a request for reconsideration, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the QIC considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of

liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party to the redetermination filed a valid and timely request for reconsideration under §§405.962 and 405.964.

(5) When a party filing for the reconsideration submits a written request of withdrawal to the QIC and satisfies the criteria set forth in paragraph (a) of this section before the reconsideration has been issued; or

(6) When the contractor has not issued a redetermination on the initial determination for which a reconsideration is sought.

(c) *Notice of dismissal.* A QIC mails or otherwise transmits written notice of the dismissal of the reconsideration request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action. The appeal will proceed with respect to any other parties that have filed a timely request for reconsideration.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a QIC may vacate its dismissal of a request for reconsideration within 6 months of the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ under §405.1004 or vacated under paragraph (d) of this section. The dismissal of a request for reconsideration of a contractor's dismissal of a redetermination request is binding and not subject to further review unless vacated under paragraph (d) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

§405.974 Reconsideration.

(a) *Reconsideration of a contractor determination.* Except as provided in §405.972, upon the basis of the evidence of record, the QIC must issue a reconsideration affirming or reversing, in whole or in part, the initial determination, including the redetermination, in question.

(b) *Reconsideration of contractor's dismissal of a redetermination request.* (1) A party to a contractor's dismissal of a request for redetermination has a right to have the dismissal reviewed by a QIC, if the party files a written request for review of the dismissal with the QIC within 60 calendar days after receipt of the contractor's notice of dismissal.

(i) For purposes of this section, the date of receipt of the contractor's notice of dismissal is presumed to be 5 calendar days after the date of the notice of dismissal, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the QIC indicated on the notice of dismissal.

(2) If the QIC determines that the contractor's dismissal was in error, it vacates the dismissal and remands the case to the contractor for a redetermination.

(3) A QIC's reconsideration of a contractor's dismissal of a redetermination request is binding and not subject to further review.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009]

§405.976 Notice of a reconsideration.

(a) *Notification to parties*—(1) *General rules.* (i) Written notice of the reconsideration must be mailed or otherwise transmitted to all parties at their last known addresses, in accordance with the timeframes established in §405.970(a) or (b).

(ii) The notice must be written in a manner reasonably calculated to be understood by a beneficiary.

(iii) The QIC must promptly notify the entity responsible for payment of claims under Part A or Part B of its reconsideration. If the reconsideration results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.* In an overpayment case involving multiple beneficiaries who have no liability, the QIC may issue a written notice only to the appellant.

(b) *Content of the notice.* The reconsideration must be in writing and contain—

(1) A clear statement indicating whether the reconsideration is favorable or unfavorable;

(2) A summary of the facts, including as appropriate, a summary of the clinical or scientific evidence used in making the reconsideration;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies, apply to the facts of the case, including, where applicable, the rationale for declining to follow an LCD, LMRP, or CMS program guidance;

(4) In the case of a determination on whether an item or service is reasonable or necessary under section 1862(a)(1)(A) of the Act, an explanation of the medical and scientific rationale for the decision;

(5) A summary of the rationale for the reconsideration.

(i) If the notice of redetermination indicated that specific documentation should be submitted with the reconsideration request, and the documentation was not submitted with the request for reconsideration, the summary must indicate how the missing documentation affected the reconsideration; and

(ii) The summary must also specify that, consistent with §§ 405.956(b)(8) and 405.966(b), all evidence, including evidence requested in the notice of redetermination, that is not submitted prior to the issuance of the reconsideration will not be considered at an ALJ level, or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. This requirement does not apply to beneficiaries, unless the beneficiary is represented by a provider or supplier or to State Medicaid Agencies;

(6) Information concerning to the parties' right to an ALJ hearing, including the applicable amount in controversy requirement and aggregation provisions;

(7) A statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable;

(8) A description of the procedures that a party must follow in order to obtain an ALJ hearing of an expedited reconsideration, including the time frame under which a request for an ALJ hearing must be filed;

(9) If appropriate, advice as to the requirements for use of the expedited access to judicial review process set forth in § 405.990;

(10) The procedures for obtaining additional information concerning the reconsideration, such as specific provisions of the policy, manual, or regulation used in making the reconsideration; and

(11) Any other requirements specified by CMS.

§ 405.978 Effect of a reconsideration.

A reconsideration is binding on all parties, unless—

(a) An ALJ decision is issued in accordance to a request for an ALJ hearing made in accordance with § 405.1014;

(b) A review entity issues a decision in accordance to a request for expedited access to judicial review under § 405.990; or

(c) The reconsideration is revised as a result of a reopening in accordance with § 405.980.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

REOPENINGS

§ 405.980 Reopening of initial determinations, redeterminations, reconsiderations, hearings, and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a binding determination or decision that resulted in either an overpayment or underpayment, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. That action may be taken by—

(i) A contractor to revise the initial determination or redetermination;

(ii) A QIC to revise the reconsideration;

(iii) An ALJ to revise the hearing decision; or

(iv) The MAC to revise the hearing or review decision.

(2) If a contractor issues a denial of a claim because it did not receive requested documentation during medical review and the party subsequently requests a redetermination, the contractor must process the request as a reopening.

(3) Notwithstanding paragraph (a)(4) of this section, a contractor must process clerical errors (which includes minor errors and omissions) as reopenings, instead of as redeterminations as specified in § 405.940. If the contractor receives a request for reopening and disagrees that the issue is a clerical error, the contractor must dismiss the reopening request and advise the party of any appeal rights, provided the timeframe to request an appeal on the original denial has not expired. For purposes of this section, clerical error includes human or mechanical errors on the part of the party or the contractor such as—

(i) Mathematical or computational mistakes;

(ii) Inaccurate data entry; or

(iii) Denials of claims as duplicates.

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, hearing, or MAC review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ, or MAC may reopen as set forth in this section.

(5) The contractor's, QIC's, ALJ's, or MAC's decision on whether to reopen is binding and not subject to appeal.

(6) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for services or items that were already reimbursed by the Medicare program is not a reopening, except where the recovery claim is based upon a provider's or supplier's failure to demonstrate that it filed a proper claim as defined in part 411 of this chapter.

(b) *Time frames and requirements for reopening initial determinations and redeterminations initiated by a contractor.* A contractor may reopen an initial determination or redetermination on its own motion—

(1) Within 1 year from the date of the initial determination or redetermination for any reason.

(2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in § 405.986.

(3) At any time if there exists reliable evidence as defined in § 405.902 that the initial determination was procured by fraud or similar fault as defined in § 405.902.

(4) At anytime if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.

(5) At any time to effectuate a decision issued under the coverage appeals process.

(c) *Time frame and requirements for reopening initial determinations and redeterminations requested by a party.* (1) A party may request that a contractor reopen its initial determination or redetermination within 1 year from the date of the initial determination or redetermination for any reason.

(2) A party may request that a contractor reopen its initial determination or redetermination within 4 years from the date of the initial determination or redetermination for good cause in accordance with § 405.986.

(3) A party may request that a contractor reopen its initial determination at any time if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based. Third party payer error does not constitute clerical error. See § 405.986(c).

(4) A party may request that a contractor reopen an initial determination for the purpose of reporting and returning an overpayment under § 401.305 of this chapter.

(d) *Time frame and requirements for reopening reconsiderations, hearing decisions and reviews initiated by a QIC, ALJ, or the MAC.* (1) A QIC may reopen its reconsideration on its own motion within 180 calendar days from the date of the reconsideration for good cause in accordance with § 405.986. If the QIC's reconsideration was procured by fraud

or similar fault, then the QIC may reopen at any time.

(2) An ALJ or the MAC may reopen a hearing decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 405.986. If the hearing decision was procured by fraud or similar fault, then the ALJ or the MAC may reopen at any time.

(3) The MAC may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986. If the MAC's decision was procured by fraud or similar fault, then the MAC may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, hearing decisions, and reviews requested by a party*. (1) A party to a reconsideration may request that a QIC reopen its reconsideration within 180 calendar days from the date of the reconsideration for good cause in accordance with § 405.986.

(2) A party to a hearing may request that an ALJ or the MAC reopen a hearing decision within 180 calendar days from the date of the hearing decision for good cause in accordance with § 405.986.

(3) A party to a review may request that the MAC reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 81 FR 7684, Feb. 12, 2016]

§ 405.982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings*. When any determination or decision is reopened and revised as provided in § 405.980, the contractor, QIC, ALJ, or the MAC must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

(b) *Reopenings initiated at the request of a party*. The contractor, QIC, ALJ, or the MAC must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

§ 405.984 Effect of a revised determination or decision.

(a) *Initial determinations*. The revision of an initial determination is binding upon all parties unless a party files a written request for a redetermination that is accepted and processed in accordance with § 405.940 through § 405.958.

(b) *Redeterminations*. The revision of a redetermination is binding upon all parties unless a party files a written request for a QIC reconsideration that is accepted and processed in accordance with § 405.960 through § 405.978.

(c) *Reconsiderations*. The revision of a reconsideration is binding upon all parties unless a party files a written request for an ALJ hearing that is accepted and processed in accordance with § 405.1000 through § 405.1064.

(d) *ALJ Hearing decisions*. The revision of a hearing decision is binding upon all parties unless a party files a written request for a MAC review that is accepted and processed in accordance with § 405.1100 through § 405.1130.

(e) *MAC review*. The revision of a MAC review is binding upon all parties unless a party files a civil action in which a Federal district court accepts jurisdiction and issues a decision.

(f) *Appeal of only the portion of the determination or decision revised by the reopening*. Only the portion of the initial determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* A revised determination or decision is binding unless it is appealed or otherwise reopened.

§ 405.986 Good cause for reopening.

(a) *Establishing good cause.* Good cause may be established when—

(1) There is new and material evidence that—

(i) Was not available or known at the time of the determination or decision; and

(ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

(b) *Change in substantive law or interpretative policy.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, or a change in legal interpretation or policy by SSA in a regulation, SSA ruling, or SSA general instruction in entitlement appeals, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision under this section. This provision does not preclude contractors from conducting reopenings to effectuate coverage decisions issued under the authority granted by section 1869(f) of the Act.

(c) *Third party payer error.* A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

EXPEDITED ACCESS TO JUDICIAL REVIEW

§ 405.990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.* (1) For purposes of this section, a "review entity" means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board (DAB), as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the Medicare Appeals Council (MAC) does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) A party may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request.* (1) A party may request EAJR in place of an ALJ hearing or MAC review if the following conditions are met:

(i) A QIC has made a reconsideration determination and the party has filed a request for—

(A) An ALJ hearing in accordance with § 405.1002 and a decision, dismissal order, or remand order of the ALJ has not been issued;

(B) MAC review in accordance with § 405.1102 and a final decision, dismissal order, or remand order of the MAC has not been issued; or

(ii) The appeal has been escalated from the QIC to the ALJ level after the period described in § 405.970(a) and § 405.970(b) has expired, and the QIC does not issue a decision or dismissal order within the timeframe described in § 405.970(e).

(2) The requestor is a party, as defined in paragraph (e) of this section.

(3) The amount remaining in controversy meets the requirements of § 405.1006(b) or (c).

(4) If there is more than one party to the reconsideration, hearing, or MAC review, each party concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.

(c) *Content of the request for EAJR.* The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the requestor considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the requestor is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation or national coverage determination and specify the statutory provision that the requestor considers unconstitutional or the provision of a regulation or a national coverage determination that the requestor considers invalid, or

(ii) A CMS Ruling that the requester considers invalid;

(3) Include a copy of any QIC reconsideration and of any ALJ hearing decision that the requester has received;

(4) If any QIC reconsideration or ALJ hearing decision was based on facts that the requestor is disputing, state why the requestor considers those facts to be immaterial; and

(5) If any QIC reconsideration or ALJ hearing decision was based on a provision of a law, regulation, national coverage determination or CMS Ruling in addition to the one the requestor considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary.

(d) *Place and time for an EAJR request*—(1) *Method and place for filing request.* The requestor may include an EAJR request in his or her request for an ALJ hearing or MAC review, or, if an appeal is already pending with an ALJ or the MAC, file a written EAJR request with the ALJ hearing office or MAC where the appeal is being considered. The ALJ hearing office or MAC forwards the request to the review entity within 5 calendar days of receipt.

(2) *Time of filing request.* The party may file a request for the EAJR—

(i) If the party has requested a hearing, at any time before receipt of the notice of the ALJ's decision; or

(ii) If the party has requested MAC review, at any time before receipt of notice of the MAC's decision.

(e) *Parties to the EAJR.* The parties to the EAJR are the persons or entities who were parties to the QIC's reconsideration determination and, if applicable, to the ALJ hearing.

(f) *Determination on EAJR request.* (1) The review entity described in paragraph (a) of this section will determine whether the request for EAJR meets all of the requirements of paragraphs (b), (c), and (d) of this section.

(2) Within 60 calendar days after the date the review entity receives a request and accompanying documents and materials meeting the conditions in paragraphs (b), (c), and (d) of this section, the review entity will issue either a certification in accordance to paragraph (g) of this section or a denial of the request.

(3) A determination by the review entity either certifying that the requirements for EAJR are met pursuant to paragraph (g) of this section or denying the request is not subject to review by the Secretary.

(4) If the review entity fails to make a determination within the time frame specified in paragraph (f)(2) of this section, then the requestor may bring a civil action in Federal district court within 60 calendar days of the end of the time frame.

(g) *Certification by the review entity.* If a party meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (g)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation, CMS Ruling, or national coverage determination;

(4) But for the provision challenged, the requestor would receive a favorable decision on the ultimate issue (such as whether a claim should be paid); and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(h) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (g) of this section—

(1) The party that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The requestor has 60 calendar days, beginning on the date of the review entity's certification within which to bring a civil action in Federal district court.

(3) The requestor must satisfy the requirements for venue under section 1869(b)(2)(C)(iii) of the Act, as well as the requirements for filing a civil action in a Federal district court under § 405.1136(a) and § 405.1136(c) through § 405.1136(f).

(i) *Rejection of EAJR.* (1) If a request for EAJR request does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises in writing all parties that the request has been denied, and returns the request to the ALJ hearing office or the MAC, which will treat it as a request for hearing or for MAC review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to an ALJ hearing office or the MAC, the appeal is considered timely filed and the 90 calendar day decision making time frame begins on the day the request is received by the hearing office or the MAC.

(j) *Interest on any amounts in controversy.* (1) If a provider or supplier is granted judicial review in accordance with this section, the amount in controversy, if any, is subject to annual interest beginning on the first day of the first month beginning after the 60 calendar day period as determined in accordance with paragraphs (f)(4) or (h)(2) of this section, as applicable.

(2) The interest is awarded by the reviewing court and payable to a prevailing party.

(3) The rate of interest is equal to the rate of interest applicable to obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this subpart is commenced.

(4) No interest awarded in accordance with this paragraph shall be income or cost for purposes of determining reimbursement due to providers or suppliers under Medicare.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009]

ALJ HEARINGS

§ 405.1000 Hearing before an ALJ: General rule.

(a) If a party is dissatisfied with a QIC's reconsideration or if the adjudication period specified in § 405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing.

(b) A hearing may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, a representative of CMS or its contractor may participate in or join the hearing as a party. (*See*, § 405.1010 and § 405.1012.)

(d) The ALJ conducts a *de novo* review and issues a decision based on the hearing record.

(e) If all parties to the hearing waive their right to appear at the hearing in person or by telephone or video-teleconference, the ALJ may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide to appear.

(g) An ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

§ 405.1002 Right to an ALJ hearing.

(a) A party to a QIC reconsideration may request a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 calendar days after receipt of the notice of the QIC's reconsideration.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the reconsideration, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the entity specified in the QIC's reconsideration.

(b) A party who files a timely appeal before a QIC and whose appeal continues to be pending before a QIC at the end of the period described in § 405.970 has a right to a hearing before an ALJ if—

(1) The party files a written request with the QIC to escalate the appeal to the ALJ level after the period described in § 405.970(a) and (b) has expired and the party files the request in accordance with § 405.970(d);

(2) The QIC does not issue a decision or dismissal order within 5 calendar days of receiving the request for escalation in accordance with § 405.970(e)(2); and

(3) The party has an amount remaining in controversy specified in § 405.1006.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009]

§ 405.1004 Right to ALJ review of QIC notice of dismissal.

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ if—

(1) The party files a written request for an ALJ review within 60 calendar days after receipt of the notice of the QIC's dismissal.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the QIC's dismissal is presumed to be 5 calendar days after the date of the dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the entity specified in the QIC's dismissal.

(b) If the ALJ determines that the QIC's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC for a reconsideration.

(c) An ALJ's decision regarding a QIC's dismissal of a reconsideration request is binding and not subject to further review. The dismissal of a request for ALJ review of a QIC's dismissal of a reconsideration request is binding and not subject to further review, unless vacated by the MAC under § 405.1108(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009]

§ 405.1006 Amount in controversy required to request an ALJ hearing and judicial review.

(a) *Definitions.* For the purposes of aggregating claims to meet the amount in controversy requirement for an ALJ hearing or judicial review:

(1) ''Common issues of law and fact'' means the claims sought to be aggregated are denied, or payment is reduced, for similar reasons and arise from a similar fact pattern material to the reason the claims are denied or payment is reduced.

(2) ''Delivery of similar or related services'' means like or coordinated services or items provided to one or more beneficiaries.

(b) *ALJ review.* To be entitled to a hearing before an ALJ, the party must meet the amount in controversy requirements of this section.

(1) For ALJ hearing requests, the required amount remaining in controversy must be $100 increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

(2) If the figure in paragraph (b)(1) of this section is not a multiple of $10, then it is rounded to the nearest multiple of $10. The Secretary will publish changes to the amount in controversy requirement in the FEDERAL REGISTER when necessary.

(c) *Judicial review.* To be entitled to judicial review, a party must meet the amount in controversy requirements of this subpart at the time it requests judicial review.

(1) For review requests, the required amount remaining in controversy must be $1,000 or more, adjusted as specified in paragraphs (b)(1) and (b)(2) of this section.

(2) [Reserved]

(d) *Calculating the amount remaining in controversy.* (1) The amount remaining in controversy is computed as the actual amount charged the individual for the items and services in question, reduced by—

(i) Any Medicare payments already made or awarded for the items or services; and

(ii) Any deductible and coinsurance amounts applicable in the particular case.

(2) Notwithstanding paragraph (d)(1) of this section, when payment is made for items or services under section 1879 of the Act or §411.400 of this chapter, or the liability of the beneficiary for those services is limited under §411.402 of this chapter, the amount in controversy is computed as the amount that the beneficiary would have been charged for the items or services in question if those expenses were not paid under §411.400 of this chapter or if that liability was not limited under §411.402 of this chapter, reduced by any deductible and coinsurance amounts applicable in the particular case.

(e) *Aggregating claims to meet the amount in controversy*—(1) *Appealing QIC reconsiderations to the ALJ level.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were previously reconsidered by a QIC;

(ii) The request for ALJ hearing lists all of the claims to be aggregated and is filed within 60 calendar days after receipt of all of the reconsiderations being appealed; and

(iii) The ALJ determines that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level to the ALJ level.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were pending before the QIC in conjunction with the same request for reconsideration;

(ii) The appellant(s) requests aggregation of the claims to the ALJ level in the same request for escalation; and

(iii) The ALJ determines that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(f) *Content of request for aggregation.* When an appellant(s) seeks to aggregate claims in a request for an ALJ hearing, the appellant(s) must—

(1) Specify all of the claims the appellant(s) seeks to aggregate; and

(2) State why the appellant(s) believes that the claims involve common issues of law and fact or delivery of similar or related services.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009]

§405.1008 Parties to an ALJ hearing.

(a) *Who may request a hearing.* Any party to the QIC's reconsideration may request a hearing before an ALJ. However, only the appellant (that is, the party that filed and maintained the request for reconsideration by a QIC) may request that the appeal be escalated to the ALJ level if the QIC does not complete its action within the time frame described in §405.970.

(b) *Who are parties to the ALJ hearing.* The party who filed the request for hearing and all other parties to the reconsideration are parties to the ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in §405.1012.

§ 405.1010 When CMS or its contractors may participate in an ALJ hearing.

(a) An ALJ may request, but may not require, CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any. CMS and/or one or more of its contractors may also elect to participate in the hearing process.

(b) If CMS or one or more of its contractors elects to participate, it advises the ALJ, the appellant, and all other parties identified in the notice of hearing of its intent to participate no later than 10 calendar days after receiving the notice of hearing.

(c) Participation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

(d) When CMS or its contractor participates in an ALJ hearing, the agency or its contractor may not be called as a witness during the hearing.

(e) CMS or its contractor must submit any position papers within the time frame designated by the ALJ.

(f) The ALJ cannot draw any adverse inferences if CMS or a contractor decides not to participate in any proceedings before an ALJ, including the hearing.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009]

§ 405.1012 When CMS or its contractors may be a party to a hearing.

(a) CMS and/or one or more of its contractors may be a party to an ALJ hearing unless the request for hearing is filed by an unrepresented beneficiary.

(b) CMS and/or the contractor(s) advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing.

(c) When CMS or one or more of its contractors participate in a hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or its contractor(s), when acting as parties, may also submit additional evidence to the ALJ within the time frame designated by the ALJ.

(d) The ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inferences if CMS or a contractor decides not to enter as a party.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009]

§ 405.1014 Request for an ALJ hearing.

(a) *Content of the request.* The request for an ALJ hearing must be made in writing. The request must include all of the following—

(1) The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed.

(2) The name and address of the appellant, when the appellant is not the beneficiary.

(3) The name and address of the designated representatives if any.

(4) The document control number assigned to the appeal by the QIC, if any.

(5) The dates of service.

(6) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(7) A statement of any additional evidence to be submitted and the date it will be submitted.

(b) *When and where to file.* The request for an ALJ hearing after a QIC reconsideration must be filed—

(1) Within 60 calendar days from the date the party receives notice of the QIC's reconsideration;

(2) With the entity specified in the QIC's reconsideration. The appellant must also send a copy of the request for hearing to the other parties. Failure to do so will toll the ALJ's 90 calendar day adjudication deadline until all parties to the QIC reconsideration receive notice of the requested ALJ hearing. If the request for hearing is timely filed with an entity other than the entity specified in the QIC's reconsideration, the deadline specified in § 405.1016 for deciding the appeal begins on the date the entity specified in the QIC's reconsideration receives the request for hearing. If the request for hearing is filed with an entity, other

than the entity specified in the QIC's reconsideration, the ALJ hearing office must notify the appellant of the date of receipt of the request and the commencement of the 90 calendar day adjudication time frame.

(c) *Extension of time to request a hearing.* (1) If the request for hearing is not filed within 60 calendar days of receipt of the QIC's reconsideration, an appellant may request an extension for good cause (See §§ 405.942(b)(2) and 405.942(b)(3)).

(2) Any request for an extension of time must be in writing, give the reasons why the request for a hearing was not filed within the stated time period, and must be filed with the entity specified in the notice of reconsideration.

(3) If the ALJ finds there is good cause for missing the deadline, the time period for filing the hearing request will be extended. To determine whether good cause for late filing exists, the ALJ uses the standards set forth in §§ 405.942(b)(2) and 405.942(b)(3).

(4) If a request for hearing is not timely filed, the adjudication period in § 405.1016 begins the date the ALJ grants the request to extend the filing deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009]

§ 405.1016 Time frames for deciding an appeal before an ALJ.

(a) When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, the ALJ must issue a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the entity specified in the QIC's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(b) The adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the entity specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ grants any extension to the filing deadline.

(c) When an appeal is escalated to the ALJ level because the QIC has not issued a reconsideration determination within the period specified in § 405.970, the ALJ must issue a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180 calendar day period beginning on the date that the request for escalation is received by the ALJ hearing office, unless the 180 calendar day period is extended as provided in this subpart.

(d) When CMS or its contractor is a party to an ALJ hearing and a party requests discovery under § 405.1037 against another party to the hearing, the adjudication periods discussed in paragraphs (a) and (c) of this section are tolled.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009]

§ 405.1018 Submitting evidence before the ALJ hearing.

(a) Except as provided in this section, parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 calendar days of receiving the notice of hearing).

(b) If a party submits written evidence later than 10 calendar days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received is not counted toward the adjudication deadline specified in § 405.1016.

(c) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see § 405.1028).

(d) The requirements of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65335, Dec. 9, 2009]

§ 405.1020 Time and place for a hearing before an ALJ.

(a) *General.* The ALJ sets the time and place for the hearing, and may

change the time and place, if necessary.

(b) *Determining how appearances are made.* The ALJ will direct that the appearance of an individual be conducted by videoteleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance. The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for one or more of the parties. The ALJ, with the concurrence of the Managing Field Office ALJ, may determine that an in-person hearing should be conducted if—

(1) VTC technology is not available; or

(2) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) The ALJ sends a notice of hearing to all parties that filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination, and the QIC that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing (and any potential participant from CMS or its contractor who wishes to attend the hearing) to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing; or

(ii) Objecting to the proposed time and/or place of the hearing.

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record. As provided in § 405.1000, the ALJ may require the parties to attend a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) *A party's objection to time and place of hearing.* (1) If a party objects to the time and place of the hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The party must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The request must be in writing.

(4) The ALJ may change the time or place of the hearing if the party has good cause. (Section 405.1052(a)(2) provides the procedures the ALJ follows when a party does not respond to a notice of hearing and fails to appear at the time and place of the hearing.)

(f) *Good cause for changing the time or place.* The ALJ can find good cause for changing the time or place of the scheduled hearing and reschedule the hearing if the information available to the ALJ supports the party's contention that—

(1) The party or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing; or

(3) Good cause exists as set forth in paragraph (g) of this section.

(g) *Good cause in other circumstances.* (1) In determining whether good cause exists in circumstances other than those set forth in paragraph (f) of this section, the ALJ considers the party's reason for requesting the change, the facts supporting the request, and the impact of the proposed change on the efficient administration of the hearing process.

(2) Factors evaluated to determine the impact of the change include, but are not limited to, the effect on processing other scheduled hearings, potential delays in rescheduling the hearing, and whether any prior changes were granted the party.

(3) Examples of other circumstances a party might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The party has attempted to obtain a representative but needs additional time.

(ii) The party's representative was appointed within 10 calendar days of the scheduled hearing and needs additional time to prepare for the hearing.

(iii) The party's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing.

(iv) A witness who will testify to facts material to a party's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for a party to travel to the hearing.

(vi) The party is unrepresented, and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) that he or she has.

(h) *Effect of rescheduling hearing*. If a hearing is postponed at the request of the appellant for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication deadline specified in § 405.1016.

(i) *A party's request for an in-person hearing*. (1) If a party objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request an in-person hearing.

(2) The party must state the reason for the objection and state the time or place he or she wants the hearing to be held.

(3) The request must be in writing.

(4) When a party's request for an in-person hearing as specified under paragraph (i)(1) of this section is granted, the ALJ must issue a decision within the adjudication timeframe specified in § 405.1016 (including any applicable extensions provided in this subpart) unless the party requesting the hearing agrees to waive such adjudication timeframe in writing.

(5) The ALJ may grant the request, with the concurrence of the Managing Field Office ALJ, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person before the ALJ.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65335, Dec. 9, 2009]

§ 405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice*. After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed to the parties and other potential participants, as provided in § 405.1020(c) at their last known address, or given by personal service. The ALJ is not required to send a notice of hearing to a party who indicates in writing that it does not wish to receive this notice. The notice is mailed or served at least 20 calendar days before the hearing.

(b) *Notice information*. (1) The notice of hearing contains a statement of the specific issues to be decided and will inform the parties that they may designate a person to represent them during the proceedings.

(2) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that, if the appellant fails to appear at the scheduled hearing without good cause, the ALJ may dismiss the hearing request, and other information about the scheduling and conduct of the hearing.

(3) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(4) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at § 405.1020(i) for notifying the ALJ of their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration, or their representative does not acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the party for an explanation.

(2) If the party states that he or she did not receive the notice of hearing, an amended notice is sent to him or her by certified mail or e-mail, if available. (See § 405.1052 for the procedures the ALJ follows in deciding if the time or place of a scheduled hearing will be changed if a party does not respond to the notice of hearing).

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009]

§ 405.1024 Objections to the issues.

(a) If a party objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 calendar days before the hearing.

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties to the appeal.

(c) The ALJ makes a decision on the objections either in writing or at the hearing.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009]

§ 405.1026 Disqualification of the ALJ.

(a) An ALJ cannot conduct a hearing if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing. The ALJ considers the party's objections and decides whether to proceed with the hearing or withdraw.

(c) If the ALJ withdraws, another ALJ will be appointed to conduct the hearing. If the ALJ does not withdraw, the party may, after the ALJ has issued an action in the case, present his or her objections to the MAC in accordance with § 405.1100 et seq. The MAC will then consider whether the hearing decision should be revised or a new hearing held before another ALJ. If the case is escalated to the MAC after a hearing is held but before the ALJ issues a decision, the MAC considers the reasons the party objected to the ALJ during its review of the case and, if the MAC deems it necessary, may remand the case to another ALJ for a hearing and decision.

§ 405.1028 Prehearing case review of evidence submitted to the ALJ.

(a) *Examination of any new evidence.* After a hearing is requested but before it is held, the ALJ will examine any new evidence submitted with the request for hearing (or within 10 calendar days of receiving the notice of hearing) as specified in § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the ALJ level.

(b) *Determining if good cause exists.* An ALJ finds good cause, for example, when the new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration.

(c) *If good cause does not exist.* If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(d) *Notification to all parties.* As soon as possible, but no later than the start of the hearing, the ALJ must notify all parties that the evidence is excluded from the hearing.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009]

§ 405.1030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* At the hearing, the ALJ fully examines the issues, questions the parties and other witnesses, and may accept documents that are material to the issues consistent with §§ 405.1018 and 405.1028.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause for not producing the evidence earlier.

(d) *Good cause exists.* If good cause exists, the ALJ considers the evidence in deciding the case and the adjudication period specified in § 405.1016 is tolled from the date of the hearing to the date the evidence is submitted.

(e) *Good cause does not exist.* If the ALJ determines that there was not good cause for not submitting the evidence sooner, the evidence is excluded.

(f) *Reopen the hearing.* The ALJ may also reopen the hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence pursuant to § 405.986. The ALJ may decide when the evidence is presented and when the issues are discussed.

§ 405.1032 Issues before an ALJ.

(a) *General rule.* The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term ''party'' does not include a representative of CMS or one of its contractors that may be participating in the hearing.) However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing.

(b) *New issues*—(1) *General.* The ALJ may consider a new issue at the hearing if he or she notifies all of the parties about the new issue any time before the start of the hearing. The new issue may include issues resulting from the participation of CMS at the ALJ level of adjudication and from any evidence and position papers submitted by CMS for the first time to the ALJ. The ALJ or any party may raise a new issue; however, the ALJ may only consider a new issue if its resolution—

(i) Could have a material impact on the claim or claims that are the subject of the request for hearing; and

(ii) Is permissible under the rules governing reopening of determinations and decisions (see § 405.980).

(2) [Reserved]

(c) *Adding claims to a pending appeal.* An ALJ cannot add any claim, including one that is related to an issue that is appropriately before an ALJ, to a pending appeal unless it has been adjudicated at the lower appeals levels and all parties are notified of the new issue(s) before the start of the hearing.

§ 405.1034 When an ALJ may remand a case to the QIC.

(a) *General rules.* (1) If an ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, then the ALJ may either:

(i) Remand the case to the QIC that issued the reconsideration or

(ii) Retain jurisdiction of the case and request that the contractor forward the missing information to the appropriate hearing office.

(2) If the information is not information that can be provided only by CMS or its contractors, the ALJ must retain jurisdiction of the case and obtain the information on his or her own, or directly from one of the parties.

(3) ''Can be provided only by CMS or its contractors'' means the information is not publicly available, and is not in the possession of, and cannot be requested and obtained by one of the parties. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. It includes, but is not limited to, information available on a CMS or contractor Web site or information in an official CMS or DHHS publication (including, but not limited to, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions).

(b) *ALJ remands a case to a QIC.* Consistent with § 405.1004 (b), the ALJ will

remand a case to the appropriate QIC if the ALJ determines that a QIC's dismissal of a request for reconsideration was in error.

(c) *Relationship to local and national coverage determination appeals process.* (1) The ALJ remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1).

(2) Unless the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1), the ALJ applies the LCD or NCD in place on the date the item or service was provided.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009]

§ 405.1036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) Any party to a hearing has the right to appear before the ALJ to present evidence and to state his or her position. A party may appear by video-teleconferencing (VTC), telephone, or in person as determined under § 405.1020.

(2) A party may also make his or her appearance by means of a representative, who may make the appearance by VTC, telephone, or in person, as determined under § 405.1020.

(3) Witness testimony may be given and CMS participation may also be accomplished by VTC, telephone, or in person, as determined under § 405.1020.

(b) *Waiver of the right to appear.* (1) A party may send the ALJ a written statement indicating that he or she does not wish to appear at the hearing.

(2) The appellant may subsequently withdraw his or her waiver at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the appellant agrees to an extension of the adjudication period as specified in § 405.1016 that may be necessary to schedule and hold the hearing.

(3) Other parties may withdraw their waiver up to the date of the scheduled hearing, if any. Even if all of the parties waive their right to appear at a hearing, the ALJ may require them to attend an oral hearing if he or she believes that a personal appearance and testimony by the appellant or any other party is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* A party or a person designated to act as a party's representative may appear before the ALJ to state the party's case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record. A copy of any written statements must be provided to the other parties to a hearing, if any, at the same time they are submitted to the ALJ.

(d) *Waiver of adjudication period.* At any time during the hearing process, the appellant may waive the adjudication deadline specified in § 405.1016 for issuing a hearing decision. The waiver may be for a specific period of time agreed upon by the ALJ and the appellant.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court.

(f) *Subpoenas.* (1) Except as provided in this section, when it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative or at the request of a party, issue subpoenas for the appearance and testimony of witnesses and for a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. An ALJ may not issue a subpoena to CMS or its contractors, on his or her own initiative or at the request of a party, to compel an appearance, testimony, or the production of evidence.

(2) A party's written request for a subpoena must—

(i) Give the names of the witnesses or documents to be produced;

(ii) Describe the address or location of the witnesses or documents with sufficient detail to find them;

(iii) State the important facts that the witness or document is expected to prove; and

(iv) Indicate why these facts cannot be proven without issuing a subpoena.

(3) Parties to a hearing who wish to subpoena documents or witnesses must file a written request for the issuance

of a subpoena with the requirements set forth in paragraph (f)(2) of this section with the ALJ no later than the end of the discovery period established by the ALJ under § 405.1037(c).

(4) Where a party has requested a subpoena, a subpoena will be issued only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted by the ALJ; and

(iv) Nevertheless, has not received the requested discovery.

(5) Reviewability of subpoena rulings—

(i) *General rule.* An ALJ ruling on a subpoena request is not subject to immediate review by the MAC. The ruling may be reviewed solely during the course of the MAC's review specified in § 405.1102, § 405.1104, or § 405.1110, as applicable. *Exception.* To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the MAC may review immediately the subpoena or that portion of the subpoena as applicable.

(ii) Where CMS objects to a discovery ruling, the MAC must take review and the discovery ruling at issue is automatically stayed pending the MAC's order.

(iii) Upon notice to the ALJ that a party or non-party, as applicable, intends to seek MAC review of the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(iv) The ALJ determines the length of the stay under the circumstances of a given case, but in no event is the stay less than 15 calendar daysbeginning after the day on which the ALJ received notice of the party or non-party's intent to seek MAC review.

(v) If the MAC grants a request for review of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until the MAC issues a written decision that affirms, reverses, or modifies the ALJ's action on the subpoena.

(vi) If the MAC does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ALJ's action stands.

(6) Enforcement. (i) If the ALJ determines, whether on his or her own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(iii) The ALJ must promptly mail a copy of the notice and related documents to the party subject to the subpoena, and to any other party and affected non-party to the appeal.

(g) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the issues and allows the parties or their designated representatives to do so.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65336, Dec. 9, 2009]

§ 405.1037 Discovery.

(a) *General rules.* (1) Discovery is permissible only when CMS or its contractor elects to participate in an ALJ hearing as a party.

(2) The ALJ may permit discovery of a matter that is relevant to the specific subject matter of the ALJ hearing, provided the matter is not privileged or otherwise protected from disclosure and the ALJ determines that the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

(3) Any discovery initiated by a party must comply with all requirements and limitations of this section, along with any further requirements or limitations ordered by the ALJ.

(b) *Limitations on discovery.* Any discovery before the ALJ is limited.

(1) A party may request of another party the reasonable production of documents for inspection and copying.

(2) A party may not take the deposition, upon oral or written examination, of another party unless the proposed deponent agrees to the deposition or the ALJ finds that the proposed deposition is necessary and appropriate in order to secure the deponent's testimony for an ALJ hearing.

(3) A party may not request admissions or send interrogatories or take any other form of discovery not permitted under this section.

(c) *Time limits.* (1) A party's discovery request is timely if the date of receipt of a request by another party is no later than the date specified by the ALJ.

(2) A party may not conduct discovery any later than the date specified by the ALJ.

(3) Before ruling on a request to extend the time for requesting discovery or for conducting discovery, the ALJ must give the other parties to the appeal a reasonable period to respond to the extension request.

(4) The ALJ may extend the time in which to request discovery or conduct discovery only if the requesting party establishes that it was not dilatory or otherwise at fault in not meeting the original discovery deadline.

(5) If the ALJ grants the extension request, it must impose a new discovery deadline and, if necessary, reschedule the hearing date so that all discoveries end no later than 45 calendar days before the hearing.

(d) *Motions to compel or for protective order.* (1) Each party is required to make a good faith effort to resolve or narrow any discovery dispute.

(2) A party may submit to the ALJ a motion to compel discovery that is permitted under this section or any ALJ order, and a party may submit a motion for a protective order regarding any discovery request to the ALJ.

(3) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute. The declaration must also be included with any response to a motion to compel or for protective order.

(4) The ALJ must decide any motion in accordance with this section and any prior discovery ruling in the appeal.

(5) The ALJ must issue and mail to each party a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part; if applicable, the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the ALJ finds necessary and appropriate.

(e) *Reviewability of discovery and disclosure rulings*—(1) *General rule.* An ALJ discovery ruling, or an ALJ disclosure ruling such as one issued at a hearing is not subject to immediate review by the MAC. The ruling may be reviewed solely during the course of the MAC's review specified in § 405.1100, § 405.1102, § 405.1104, or § 405.1110, as applicable.

(2) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the ALJ, the MAC may review that portion of the discovery or disclosure ruling immediately.

(i) Where CMS objects to a discovery ruling, the MAC must take review and the discovery ruling at issue is automatically stayed pending the MAC's order.

(ii) Upon notice to the ALJ that a party intends to seek MAC review of the ruling, the ALJ must stay all proceedings affected by the ruling.

(iii) The ALJ determines the length of the stay under the circumstances of a given case, but in no event must the length of the stay be less than 15 calendar days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek MAC review.

(iv) Where CMS requests the MAC to take review of a discovery ruling or where the MAC grants a request, made by a party other than CMS, to review a discovery ruling, the ruling is stayed until the time the MAC issues a written decision that affirms, reverses, modifies, or remands the ALJ's ruling.

(v) With respect to a request from a party, other than CMS, for review of a

discovery ruling, if the MAC does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling stands.

(f) *Adjudication time frames.* If a party requests discovery from another party to the ALJ hearing, the ALJ adjudication time frame specified in § 405.1016 is tolled until the discovery dispute is resolved.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65336, Dec. 9, 2009]

§ 405.1038 Deciding a case without a hearing before an ALJ.

(a) *Decision wholly favorable.* If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear.* (1) The ALJ may decide a case on the record and not conduct a hearing if—

(i) All the parties indicate in writing that they do not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or videoteleconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform the ALJ that he or she wants to appear, and there are no other parties who wish to appear.

(2) When a hearing is not held, the decision of the ALJ must refer to the evidence in the record on which the decision was based.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65336, Dec. 9, 2009]

§ 405.1040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) At the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the parties consent in writing. A record of the conference is made.

(d) The ALJ issues an order stating all agreements and actions resulting from the conference. If the parties do not object, the agreements and actions become part of the hearing record and are binding on all parties.

§ 405.1042 The administrative record.

(a) *Creating the record.* (1) The ALJ makes a complete record of the evidence, including the hearing proceedings, if any.

(2) The record will include marked as exhibits, the documents used in making the decision under review, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits. In the record, the ALJ must also discuss any evidence excluded under § 405.1028 and include a justification for excluding the evidence.

(3) A party may review the record at the hearing, or, if a hearing is not held, at any time before the ALJ's notice of decision is issued.

(4) If a request for review is filed or the case is escalated to the MAC, the complete record, including any recording of the hearing, is forwarded to the MAC.

(5) A typed transcription of the hearing is prepared if a party seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) A party may request and receive a copy of all or part of the record, including the exhibits list, documentary evidence, and a copy of the tape of the oral proceedings. The party may be asked to pay the costs of providing these items.

(2) If a party requests all or part of the record from the ALJ and an opportunity to comment on the record, the

time beginning with the ALJ's receipt of the request through the expiration of the time granted for the party's response does not count toward the 90 calendar day adjudication deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65336, Dec. 9, 2009]

§ 405.1044 Consolidated hearing before an ALJ.

(a) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ.

(b) It is within the discretion of the ALJ to grant or deny an appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the requests for hearing are combined. In considering the appellant's request for consolidation, the ALJ must take into account the adjudication deadlines for each case and may require an appellant to waive the adjudication deadline associated with one or more cases if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(c) The ALJ may also propose on his or her own motion to consolidate two or more cases in one hearing for administrative efficiency, but may not require an appellant to waive the adjudication deadline for any of the consolidated cases.

(d) Before consolidating a hearing, the ALJ must notify CMS of his or her intention to do so, and CMS may then elect to participate in the consolidated hearing, as a party, by sending written notice to the ALJ within 10 calendar days after receipt of the ALJ's notice of the consolidation.

(e) If the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record or a separate decision and record on each claim. The ALJ ensures that any evidence that is common to all claims and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65336, Dec. 9, 2009]

§ 405.1046 Notice of an ALJ decision.

(a) *General rule.* Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record. The ALJ mails a copy of the decision to all the parties at their last known address, to the QIC that issued the reconsideration determination, and to the contractor that issued the initial determination. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with this ALJ decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(b) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(1) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(2) The procedures for obtaining additional information concerning the decision; and

(3) Notification of the right to appeal the decision to the MAC, including instructions on how to initiate an appeal under this section.

(c) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ, the ALJ may make a finding as to the amount of payment due. If the ALJ makes a finding concerning payment when the amount of payment was not an issue before the ALJ, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's decision is not binding on the contractor for purposes of determining the amount of payment due. The amount of payment

determined by the contractor in effectuating the ALJ's decision is a new initial determination under § 405.924.

(d) *Timing of decision.* The ALJ issues a decision by the end of the 90 calendar day period beginning on the date when the request for hearing is received by the entity specified in the QIC's reconsideration, unless the 90 calendar day period is extended as provided in § 405.1016.

(e) *Recommended decision.* An ALJ issues a recommended decision if he or she is directed to do so in the MAC's remand order. An ALJ may not issue a recommended decision on his or her own motion. The ALJ mails a copy of the recommended decision to all the parties at their last known address.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65336, Dec. 9, 2009]

§ 405.1048 The effect of an ALJ's decision.

The decision of the ALJ is binding on all parties to the hearing unless—

(a) A party to the hearing requests a review of the decision by the MAC within the stated time period or the MAC reviews the decision issued by an ALJ under the procedures set forth in § 405.1110, and the MAC issues a final decision or remand order or the appeal is escalated to Federal district court under the provisions at § 405.1132 and the Federal district court issues a decision.

(b) The decision is reopened and revised by an ALJ or the MAC under the procedures explained in § 405.980;

(c) The expedited access to judicial review process at § 405.990 is used;

(d) The ALJ's decision is a recommended decision directed to the MAC and the MAC issues a decision; or

(e) In a case remanded by a Federal district court, the MAC assumes jurisdiction under the procedures in § 405.1138 and the MAC issues a decision.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65336, Dec. 9, 2009]

§ 405.1050 Removal of a hearing request from an ALJ to the MAC.

If a request for hearing is pending before an ALJ, the MAC may assume responsibility for holding a hearing by requesting that the ALJ send the hearing request to it. If the MAC holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to all parties at their last known address informing them that the MAC has assumed responsibility for the case.

§ 405.1052 Dismissal of a request for a hearing before an ALJ.

Dismissal of a request for a hearing is in accordance with the following:

(a) An ALJ dismisses a request for a hearing under any of the following conditions:

(1) At any time before notice of the hearing decision is mailed, if only one party requested the hearing and that party asks to withdraw the request. This request may be submitted in writing to the ALJ or made orally at the hearing. The request for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing and does not intend to further proceed with the appeal. If an attorney, or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

(2) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party was notified before the time set for the hearing that the request for hearing might be dismissed without further notice for failure to appear;

(ii) The party did not appear at the time and place of hearing and does not contact the ALJ hearing office within 10 calendar days and provide good cause for not appearing; or

(iii) The ALJ sends a notice to the party asking why the party did not appear; and the party does not respond to the ALJ's notice within 10 calendar days or does not provide good cause for the failure to appear.

(iv) In determining whether good cause exists under this paragraph (a)(2), the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility

with the English language), that the party may have.

(3) The person or entity requesting a hearing has no right to it under § 405.1002.

(4) The party did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 405.1014(c).

(5) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to § 405.1014.

(6) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or the MAC has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has become binding by either administrative or judicial action.

(7) The appellant abandons the request for hearing. An ALJ may conclude that an appellant has abandoned a request for hearing when the ALJ hearing office attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(b) *Notice of dismissal.* The ALJ mails a written notice of the dismissal of the hearing request to all parties at their last known address. The notice states that there is a right to request that the MAC vacate the dismissal action.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65336, Dec. 9, 2009]

§ 405.1054 Effect of dismissal of a request for a hearing before an ALJ.

The dismissal of a request for a hearing is binding, unless it is vacated by the MAC under § 405.1108(b).

APPLICABILITY OF MEDICARE COVERAGE POLICIES

§ 405.1060 Applicability of national coverage determinations (NCDs).

(a) *General rule.* (1) An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under Medicare or a determination of the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act as well as under other applicable provisions of the Act.

(4) An NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs, and the MAC.

(b) *Review by an ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

(c) *Review by the MAC.* (1) The MAC may not disregard, set aside, or otherwise review an NCD for purposes of a section 1869 claim appeal, except that the DAB may review NCDs as provided under part 426 of this title.

(2) The MAC may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ and MAC.

(a) ALJs and the MAC are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or MAC declines to follow a policy in a particular case, the ALJ or MAC decision must explain the reasons why the policy was not followed. An ALJ or MAC decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or MAC may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

§405.1063 Applicability of laws, regulations and CMS Rulings.

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and the MAC.

(b) CMS Rulings are published under the authority of the Administrator, CMS. Consistent with §401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

[74 FR 65336, Dec. 9, 2009]

§405.1064 ALJ decisions involving statistical samples.

When an appeal from the QIC involves an overpayment issue and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of the entire statistical sample used by the QIC.

MEDICARE APPEALS COUNCIL REVIEW

§405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to the hearing may request that the MAC review an ALJ's decision or dismissal.

(b) Under circumstances set forth in §§405.1104 and 405.1108, the appellant may request that a case be escalated to the MAC for a decision even if the ALJ has not issued a decision or dismissal in his or her case.

(c) When the MAC reviews an ALJ's decision, it undertakes a *de novo* review. The MAC issues a final decision or dismissal order or remands a case to the ALJ within 90 calendar days of receipt of the appellant's request for review, unless the 90 calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the ALJ level to the MAC, the MAC will issue a final decision or dismissal order or remand the case to the ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65336, Dec. 9, 2009]

§405.1102 Request for MAC review when ALJ issues decision or dismissal.

(a)(1) A party to the ALJ hearing may request a MAC review if the party files a written request for a MAC review within 60 calendar days after receipt of the ALJ's decision or dismissal.

(2) For purposes of this section, the date of receipt of the ALJ's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's action.

(b) A party requesting a review may ask that the time for filing a request for MAC review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the MAC; and

(3) It explains why the request for review was not filed within the stated time period. If the MAC finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards outlined at §§405.942(b)(2) and 405.942(b)(3).

(c) A party does not have the right to seek MAC review of an ALJ's remand to a QIC or an ALJ's affirmation of a QIC's dismissal of a request for reconsideration.

(d) For purposes of requesting MAC review (§405.1100 through §405.1140), unless specifically excepted the term, ''party,'' includes CMS where CMS has entered into a case as a party according to §405.1012. The term, ''appellant,'' does not include CMS, where CMS has entered into a case as a party according to §405.1012.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65336, Dec. 9, 2009]

§405.1104 Request for MAC review when an ALJ does not issue a decision timely.

(a) *Requesting escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period under §405.1016 may request MAC review if—

(1) The appellant files a written request with the ALJ to escalate the appeal to the MAC after the adjudication period has expired; and

(2) The ALJ does not issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in §405.1016.

(b) *Escalation.* (1) If the ALJ is not able to issue a decision, dismissal order, or remand order within the time period set forth in paragraph (a)(2) of this section, he or she sends notice to the appellant.

(2) The notice acknowledges receipt of the request for escalation, and confirms that the ALJ is not able to issue a decision, dismissal order, or remand order within the statutory timeframe.

(3) If the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of this section or does not send the required notice to the appellant, the QIC decision becomes the decision that is subject to MAC review consistent with §405.1102(a).

(c) *No escalation.* If the ALJ's adjudication period set forth in §405.1016 expires, the case remains with the ALJ until a decision, dismissal order, or remand order is issued or the appellant requests escalation to the MAC.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65337, Dec. 9, 2009]

§405.1106 Where a request for review or escalation may be filed.

(a) When a request for a MAC review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's action. The appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal who received a copy of the hearing decision under §405.1046(a) or a copy of the notice of dismissal under §405.1052(b). Failure to copy the other parties tolls the MAC's adjudication deadline set forth in §405.1100 until all parties to the hearing receive notice of the request for MAC review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the MAC's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the MAC sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the MAC level because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under §405.1016, the request for escalation must be filed with both the ALJ and the MAC. The appellant must also send a copy of the request for escalation to

the other parties. Failure to copy the other parties tolls the MAC's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for MAC review. In a case that has been escalated from the ALJ, the MAC's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the MAC.

[74 FR 65337, Dec. 9, 2009]

§ 405.1108 MAC actions when request for review or escalation is filed.

(a) Except as specified in paragraphs (c) and (d) of this section, when a party requests that the MAC review an ALJ's decision, the MAC will review the ALJ's decision *de novo*. The party requesting review does not have a right to a hearing before the MAC. The MAC will consider all of the evidence in the administrative record. Upon completion of its review, the MAC may adopt, modify, or reverse the ALJ's decision or remand the case to an ALJ for further proceedings.

(b) When a party requests that the MAC review an ALJ's dismissal, the MAC may deny review or vacate the dismissal and remand the case to the ALJ for further proceedings.

(c) The MAC will dismiss a request for review when the party requesting review does not have a right to a review by the MAC, or will dismiss the request for a hearing for any reason that the ALJ could have dismissed the request for hearing.

(d) When an appellant requests escalation of a case from the ALJ level to the MAC, the MAC may take any of the following actions:

(1) Issue a decision based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ before the case was escalated.

(2) Conduct any additional proceedings, including a hearing, that the MAC determines are necessary to issue a decision.

(3) Remand the case to an ALJ for further proceedings, including a hearing.

(4) Dismiss the request for MAC review because the appellant does not have the right to escalate the appeal.

(5) Dismiss the request for a hearing for any reason that the ALJ could have dismissed the request.

§ 405.1110 MAC reviews on its own motion.

(a) *General rule*. The MAC may decide on its own motion to review a decision or dismissal issued by an ALJ. CMS or any of its contractors may refer a case to the MAC for it to consider reviewing under this authority anytime within 60 calendar days after the date of an ALJ's decision or dismissal.

(b) *Referral of cases*. (1) CMS or any of its contractors may refer a case to the MAC if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the MAC take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the ALJ level; and

(ii) In CMS' view, the ALJ's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion.

(2) CMS' referral to the MAC is made in writing and must be filed with the MAC no later than 60 calendar days after the ALJ's decision or dismissal is issued. The written referral will state the reasons why CMS believes the MAC must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's action who received a copy of the hearing decision under § 405.1046(a) or the notice of dismissal under § 405.1052(b), and to the ALJ. Parties to the ALJ's action may file exceptions to the referral by submitting written comments to the MAC within 20 calendar days of the referral notice. A party submitting comments to the MAC must send such comments to CMS and all other parties to the ALJ's decision who received a copy of the hearing decision under § 405.1046(a) or the notice of dismissal under § 405.1052(b).

(c) *Standard of review*. (1) Referral by CMS after participation at the ALJ level. If CMS or its contractor participated in an appeal at the ALJ level,

the MAC exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the ALJ proceedings or appear as a party.* The MAC will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

(d) *MAC's action.* If the MAC decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The MAC may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request. The MAC must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The MAC may not, however, issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the MAC does not act within the applicable adjudication deadline, the ALJ's decision or dismissal is binding on the parties to the ALJ decision.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009]

§ 405.1112 Content of request for review.

(a) The request for MAC review must be filed with the MAC or appropriate ALJ hearing office. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare health insurance claim number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's decision or dismissal order, if any; if the party is requesting escalation from the ALJ to the MAC, the hearing office in which the appellant's request for hearing is pending; and the name and signature of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dismissal, or other determination being appealed. For example, if the party requesting review believes that the ALJ's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The MAC will limit its review of an ALJ's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65337, Dec. 9, 2009]

§ 405.1114 Dismissal of request for review.

The MAC dismisses a request for review if the party requesting review did not file the request within the stated period of time and the time for filing has not been extended. The MAC also dismisses the request for review if—

(a) The party asks to withdraw the request for review;

(b) The party does not have a right to request MAC review; or

(c) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(1) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the MAC considers whether the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue;

(2) No other individual or entity with a financial interest in the case wishes to pursue an appeal under § 405.1102;

(3) No other party to the ALJ hearing filed a valid and timely review request under §§ 405.1102 and 405.1112.

§ 405.1116 Effect of dismissal of request for MAC review or request for hearing.

The dismissal of a request for MAC review or denial of a request for review of a dismissal issued by an ALJ is binding and not subject to further review unless reopened and vacated by the MAC. The MAC's dismissal of a request for hearing is also binding and not subject to judicial review.

§ 405.1118 Obtaining evidence from the MAC.

A party may request and receive a copy of all or part of the record of the ALJ hearing, including the exhibits list, documentary evidence, and a copy of the tape of the oral proceedings. However, the party may be asked to pay the costs of providing these items. If a party requests evidence from the MAC and an opportunity to comment on that evidence, the time beginning with the MAC's receipt of the request for evidence through the expiration of the time granted for the party's response will not be counted toward the 90 calendar day adjudication deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009]

§ 405.1120 Filing briefs with the MAC.

Upon request, the MAC will give the party requesting review, as well as all other parties, a reasonable opportunity to file briefs or other written statements about the facts and law relevant to the case. Any party who submits a brief or statement must send a copy to all of the other parties. Unless the party requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the MAC will not be counted toward the adjudication timeframe set forth in § 405.1100. The MAC may also request, but not require, CMS or its contractor to file a brief or position paper if the MAC determines that it is necessary to resolve the issues in the case. The MAC will not draw any adverse inference if CMS or a contractor either participates, or decides not to participate in MAC review.

§ 405.1122 What evidence may be submitted to the MAC.

(a) *Appeal before the MAC on request for review of ALJ's decision.* (1) If the MAC is reviewing an ALJ's decision, the MAC limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ. However, if the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue that is submitted with the request for review.

(2) If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.

(b) *Appeal before MAC as a result of appellant's request for escalation.* (1) If the MAC is reviewing a case that is escalated from the ALJ level to the MAC, the MAC will decide the case based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ before the case was escalated.

(2) If the MAC receives additional evidence with the request for escalation that is material to the question

to be decided, or determines that additional evidence is needed to resolve the issues in the case, and the record provided to the MAC indicates that the previous decision-makers did not attempt to obtain the evidence before escalation, the MAC may remand the case to an ALJ to consider or obtain the evidence and issue a new decision.

(c) *Evidence related to issues previously considered by the QIC*. (1) If new evidence related to issues previously considered by the QIC is submitted to the MAC by a provider, supplier, or a beneficiary represented by a provider or supplier, the MAC must determine if the provider, supplier, or the beneficiary represented by a provider or supplier had good cause for submitting it for the first time at the MAC level.

(2) If the MAC determines that good cause does not exist, the MAC must exclude the evidence from the proceeding, may not consider it in reaching a decision, and may not remand the issue to an ALJ.

(3) The MAC must notify all parties if it excludes the evidence. The MAC may remand to an ALJ if—

(i) The ALJ did not consider the new evidence submitted by the provider, supplier, or beneficiary represented by a provider or supplier because good cause did not exist; and

(ii) The MAC finds that good cause existed under § 405.1028 and the ALJ should have reviewed the evidence.

(iii) The new evidence is submitted by a party that is not a provider, supplier, or a beneficiary represented by a provider or supplier.

(d) *Subpoenas*. (1) Except as provided in this section, when it is reasonably necessary for the full presentation of a case, the MAC may, on its own initiative or at the request of a party, issue subpoenas requiring a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. The MAC may not issue a subpoena to CMS or its contractors, on its own initiative or at the request of a party, to compel the production of evidence.

(2) A party's request for a subpoena must—

(i) Give a sufficient description of the documents to be produced;

(ii) State the important facts that the documents are expected to prove; and

(iii) Indicate why these facts could not be proven without issuing a subpoena.

(3) A party to the MAC review on escalation that wishes to subpoena documents must file a written request that complies with the requirements set out in paragraph (d)(2) of this section within 10 calendar days of the request for escalation.

(4) A subpoena will issue only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted; and

(iv) Nevertheless, has still not received the requested discovery.

(e) Reviewability of subpoena rulings—

(1) *General rule*. A MAC ruling on a subpoena request is not subject to immediate review by the Secretary.

(2) *Exception*. To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the MAC, the Secretary may review immediately that subpoena or portion of the subpoena.

(3) Upon notice to the MAC that a party or non-party, as applicable, intends to seek Secretary review of the subpoena, the MAC must stay all proceedings affected by the subpoena.

(4) The MAC determines the length of the stay under the circumstances of a given case, but in no event is less than 15 calendar days after the day on which the MAC received notice of the party or non-party's intent to seek Secretary review.

(5) If the Secretary grants a request for review, the subpoena or portion of the subpoena, as applicable, is stayed until the Secretary issues a written decision that affirms, reverses, modifies, or remands the MAC's action for the subpoena.

(6) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the MAC's action stands.

(f) *Enforcement*. (1) If the MAC determines, whether on its own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the MAC may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) Any enforcement request by the MAC must consist of a written notice to the Secretary describing in detail the MAC's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(3) The MAC must promptly mail a copy of the notice and related documents to the party or non-party subject to the subpoena, and to any other party and affected non-party to the appeal.

(4) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the subpoena stands.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009]

§ 405.1124 Oral argument.

A party may request to appear before the MAC to present oral argument.

(a) The MAC grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The MAC may decide on its own that oral argument is necessary to decide the issues in the case. If the MAC decides to hear oral argument, it tells the parties of the time and place of the oral argument at least 10 calendar days before the scheduled date.

(c) In case of a previously unrepresented beneficiary, a newly hired representative may request an extension of time for preparation of the oral argument and the MAC must consider whether the extension is reasonable.

(d) The MAC may also request, but not require, CMS or its contractor to appear before it if the MAC determines that it may be helpful in resolving the issues in the case.

(e) The MAC will not draw any inference if CMS or a contractor decides not to participate in the oral argument.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009]

§ 405.1126 Case remanded by the MAC.

(a) *When the MAC may remand a case*. Except as specified in § 405.1122(c), the MAC may remand a case in which additional evidence is needed or additional action by the ALJ is required. The MAC will designate in its remand order whether the ALJ will issue a decision or a recommended decision on remand.

(b) *Action by ALJ on remand*. The ALJ will take any action that is ordered by the MAC and may take any additional action that is not inconsistent with the MAC's remand order.

(c) *Notice when case is returned with a recommended decision*. When the ALJ sends a case to the MAC with a recommended decision, a notice is mailed to the parties at their last known address. The notice tells them that the case was sent to the MAC, explains the rules for filing briefs or other written statements with the MAC, and includes a copy of the recommended decision.

(d) *Filing briefs with the MAC when ALJ issues recommended decision*. (1) Any party to the recommended decision may file with the MAC briefs or other written statements about the facts and law relevant to the case within 20 calendar days of the date on the recommended decision. Any party may ask the MAC for additional time to file briefs or statements. The MAC will extend this period, as appropriate, if the party shows that it has good cause for requesting the extension.

(2) All other rules for filing briefs with and obtaining evidence from the MAC follow the procedures explained in this subpart.

(e) *Procedures before the MAC*. (1) The MAC, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(2) If the MAC determines that more evidence is required, it may again remand the case to an ALJ for further inquiry into the issues, rehearing, receipt of evidence, and another decision or recommended decision. However, if the

MAC decides that it can get the additional evidence more quickly, it will take appropriate action.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009]

§ 405.1128 Action of the MAC.

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on MAC consideration of additional evidence in § 405.1122, the MAC will make a decision or remand the case to an ALJ.

(b) The MAC may adopt, modify, or reverse the ALJ hearing decision or recommended decision.

(c) The MAC mails a copy of its decision to all the parties at their last known addresses. For overpayment cases involving multiple beneficiaries where there is no beneficiary liability the MAC may choose to send written notice only to the appellant. In the event the decision will result in a payment to a provider or supplier, the Medicare contractor must issue any electronic or paper remittance advice notice to that provider or supplier.

§ 405.1130 Effect of the MAC's decision.

The MAC's decision is final and binding on all parties unless a Federal district court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with § 405.980. A party may file an action in a Federal district court within 60 calendar days after the date it receives notice of the MAC's decision.

[74 FR 65338, Dec. 9, 2009]

§ 405.1132 Request for escalation to Federal court.

(a) If the MAC does not issue a decision or dismissal or remand the case to an ALJ within the adjudication period specified in § 405.1100, or as extended as provided in this subpart, the appellant may request that the appeal, other than an appeal of an ALJ dismissal, be escalated to Federal district court. Upon receipt of a request for escalation, the MAC may—

(1) Issue a decision or dismissal or remand the case to an ALJ, if that action is issued within the latter of 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period set forth in § 405.1100; or

(2) If the MAC is not able to issue a decision or dismissal or remand as set forth in paragraph (a)(1) of this section, it will send a notice to the appellant acknowledging receipt of the request for escalation and confirming that it is not able to issue a decision, dismissal or remand order within the statutory time frame.

(b) A party may file an action in a Federal district court within 60 calendar days after the date it receives the MAC's notice that the MAC is not able to issue a final decision, dismissal order, or remand order unless the party is appealing an ALJ dismissal.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009]

§ 405.1134 Extension of time to file action in Federal district court.

(a) Any party to the MAC's decision or to a request for EAJR that has been certified by the review entity other than CMS may request that the time for filing an action in a Federal district court be extended.

(b) The request must—

(1) Be in writing.

(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the MAC.

(c) If the party shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards specified in § 405.942(b)(2) or (b)(3).

§ 405.1136 Judicial review.

(a) *General rules.* (1) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a MAC decision, or an appellant who requests escalation to Federal district court if the MAC does not complete its review of the ALJ's decision within the applicable adjudication period, may obtain a court review if the amount remaining in controversy satisfies the requirements of § 405.1006(c).

(2) If the MAC's adjudication period set forth in § 405.1100 expires and the appellant does not request escalation

to Federal district court, the case remains with the MAC until a final decision, dismissal order, or remand order is issued.

(b) *Court in which to file civil action.* (1) Any civil action described in paragraph (a) of this section must be filed in the district court of the United States for the judicial district in which the party resides or where such individual, institution, or agency has its principal place of business.

(2) If the party does not reside within any judicial district, or if the individual, institution, or agency does not have its principal place of business within any such judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in §405.1130, §405.1132, or §405.1134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the MAC's decision or the MAC's notice that it is not able to issue a decision within the statutory timeframe shall be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in §405.990, the civil action must be filed within 60 calendar days after receipt of the review entity's certification, except where the time is extended by the ALJ or MAC, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff will be notified that he or she has named an incorrect defendant and is granted 60 calendar days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Prohibition against judicial review of certain Part B regulations or instructions.* Under section 1869(e)(1) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Medicare Part B if the regulation was published, or the instructions issued, before January 1, 1991.

(f) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

(2) When the Secretary's decision is adverse to a party due to a party's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof a party must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37705, June 30, 2005; 74 FR 65338, Dec. 9, 2009]

§405.1138 Case remanded by a Federal district court.

When a Federal district court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the MAC, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ with instructions to take action and either issue a decision, take other action, or return the case to the MAC with a recommended decision. If the MAC remands a case, the procedures specified in §405.1140 will be followed.

§405.1140 MAC review of ALJ decision in a case remanded by a Federal district court.

(a) *General rules.* (1) In accordance with §405.1138, when a case is remanded by a Federal district court for further consideration and the MAC remands the case to an ALJ, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the MAC assumes jurisdiction.

(2) The MAC may assume jurisdiction based on written exceptions to the decision of the ALJ that a party files with the MAC or based on its authority under paragraph (c) of this section.

(3) The MAC either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ for further proceedings.

(b) *A party files exceptions disagreeing with the decision of the ALJ.* (1) If a party disagrees with an ALJ decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the MAC. Exceptions may be filed by submitting a written statement to the MAC setting forth the reasons for disagreeing with the decision of the ALJ. The party must file exceptions within 30 calendar days of the date the party receives the decision of the ALJ or submit a written request for an extension within the 30 calendar day period. The MAC will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the party needs the additional time and may be granted if the MAC finds good cause under the standard established in § 405.942(b)(2) or (b)(3).

(2) If written exceptions are timely filed, the MAC considers the party's reasons for disagreeing with the decision of the ALJ. If the MAC concludes that there is no reason to change the decision of the ALJ, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ is warranted. In this instance, the decision of the ALJ is the final decision of the Secretary after remand.

(3) When a party files written exceptions to the decision of the ALJ, the MAC may assume jurisdiction at any time. If the MAC assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remanding the case to an ALJ for further proceedings, including a new decision. The new decision of the MAC is the final decision of the Secretary after remand.

(c) *MAC assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the decision of the ALJ, the MAC may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to all parties at their last known address.

(3) The parties will be provided with the opportunity to file briefs or other written statements with the MAC about the facts and law relevant to the case.

(4) After the briefs or other written statements are received or the time allowed (usually 30 calendar days) for submitting them has expired, the MAC will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ for further proceedings, including a new decision.

(d) *Exceptions are not filed and the MAC does not otherwise assume jurisdiction.* If no exceptions are filed and the MAC does not assume jurisdiction of the cases within 60 calendar days after the date of the ALJ's decision, the decision of the ALJ becomes the final decision of the Secretary after remand.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009]

Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for Inpatient Hospital Discharges

SOURCE: 69 FR 69624, Nov. 26, 2004, unless otherwise noted.

§ 405.1200 Notifying beneficiaries of provider service terminations.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1200 through 405.1204, the term, provider, is defined as a home health agency (HHA), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), or hospice.

(2) For purposes of §§ 405.1200 through 405.1204, a termination of Medicare-covered service is a discharge of a beneficiary from a residential provider of services, or a complete cessation of coverage at the end of a course of